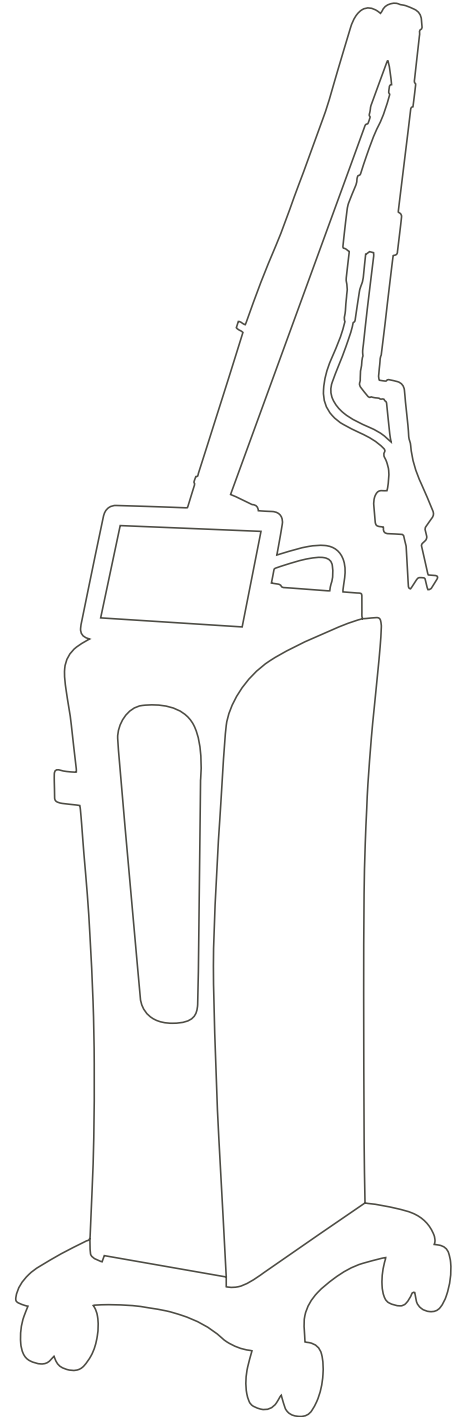




TETRA 
PRO

CLINICAL USER'S MANUAL

January 2024



DEKA
Innate Ability

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1

Introduction: CO₂ Laser: Applications in Dermatology

The development of CO₂ laser systems and the new, more sophisticated operating techniques have led to a considerable increase in potential applications for surgical lasers, which range from resurfacing treatments (ablative and fractional) to high-precision vaporization of many dermatological lesions, even in very delicate areas such as around the eyes, the outer ear, and mucous and pseudo-mucous areas.

The introduction of innovative CO₂ laser devices with different powers and pulse management systems offering full and flexible control of ablation depth, while limiting heat diffusion to the surrounding tissues and minimizing the need for local anesthetics, now make it possible to achieve new treatment frontiers.

1.1 The Action of Light

1.1.1 Laser-Tissue Interactions

On the whole, the effects of the laser beam on the tissue depend on the parameters indicated below.

- **Wavelength.** This is the most important parameter. Certain wavelengths are selectively absorbed by specific molecules present in the skin, defined as “targets” or chromophores (water, melanin, hemoglobin). This absorption generates a large amount of heat in the target (by conversion of the radiant energy – light – into thermal energy), which is able to selectively destroy the target molecules (Selective Photothermolysis) with minimal damage to the surrounding tissues.
- **Pulse duration.** The destructive capacity of a laser also depends greatly on the duration of the pulse of light it is capable of emitting. After heating, any biological structure takes a certain time to cool, and as it cools it releases heat; thus, selective destruction can be obtained only if the duration of the laser pulse is shorter than the thermal relaxation time (TRT); that is, the time it takes for a biological structure to lose 50% of its heat. Otherwise, the second pulse would cause an additional rise in temperature and due to thermal conduction, carbonize the surrounding tissues with scarring and permanent skin discoloration.
- **Laser output power and beam diameter (power density).** The effects of a laser beam on the tissue also depend on the concentration of the photons in the light beam (that is, on the relationship between the output power of the device and the beam diameter).

1.1.2 The CO₂ Laser

As water is the main skin component it plays a fundamental role in the laser/tissue interaction. The CO₂ laser emits in the far-infrared spectrum (at a 10,600-nm wavelength) where absorption of the radiation by the water molecules prevails over penetration.

Sufficiently intense irradiation will cause vaporization of the tissue due to evaporation of the water, with tissue penetration limited to a few tens of micrometers.

This characteristic, together with appropriate pulse management, allows for operating with extreme precision in vaporizing tissues in successive passes until the clinical end-point is achieved.

The main goal when using a pulsed surgical laser is to obtain ablation while limiting heat damage to a minimum. This can be obtained by vaporizing the tissue for less time than that required for the heat to propagate (namely, a time < TRT).

In order to obtain instantaneous ablation, the energy of the laser beam must exceed the vaporization threshold of the skin, below which, the only effect will be carbonization and necrosis of the tissue. This consideration is fundamental for the correct use of surgical lasers: **the least heat damage is obtained with high-power, ultra-short pulses.**

Depending on the degree and time of tissue exposure, this effect can be divided into three different mechanisms:

- **Hyperthermia**, which involves a moderate rise in temperature (only a few degrees Centigrade) above normal physiological conditions for several minutes (temperatures of between 41°C and 44°C).
- **Coagulation**, which is obtained with exposure to temperatures between 50°C and 90°C for one second at a time, producing desiccation and retraction of the tissue due to denaturation of the tissue proteins, including collagen. The tissues thus treated are removed by the operator (debridement) and the repair process begins. Coagulation is used to destroy tissues and stop bleeding (hemostasis).
- **Vaporization/ablation**, which involves an immediate loss of substance in the tissue. The different tissue constituents are eliminated at temperatures higher than 100°C for a relatively short time (a few tenths of a second). If an extremely high temperature can be reached in a very short time, then it will be possible to achieve vaporization of the target with little or no necrosis at the margins of the lesion. This phenomenon, called photoablation, entails minimally explosive photodecomposition.

INTRODUCTION

The thermal relaxation time (TRT) is the essential parameter for correct selection of the CO₂ laser settings. If the duration of the laser pulse is less than the TRT, the laser energy remains “trapped” inside the volume of irradiated tissue. The sharp rise in temperature and relative heat damage will be localized in this region, while the surrounding tissues will undergo very little heating via diffusion. If the laser irradiation time is longer, the heat will then spread inside the tissue, causing undesirable effects and unsightly scarring.

The CO₂ laser was first used in surgery as a tool for vaporizing and removing tissues and it is still the most versatile and widely-used laser system in dermatology.

The acronym WYSIWYG (What You See Is What You Get) means that the operator is capable of making a step-by-step visual assessment, using “color indicators,” of the level reached (vaporizing only the epidermis or making in-depth use of the heating effect as far as the papillary dermis or reticular dermis) and therefore of correctly evaluating the clinical end point.

The color indicators are as follows:

- Opalescent aspect with formation of micro-bubbles, accompanied by a characteristic crackling and whitening (vaporization of the epidermis);
- Flat, smooth, pink surface (penetration to the papillary dermis);
- Yellowish, hardened tissue, similar in aspect to chamois leather (papillary/reticular dermis)
- Bundles of collagen fibers, appearing macroscopically as “water-soaked cotton threads” (reticular dermis).

1.2 CO₂ Fractional Laser Resurfacing

Traditional ablative resurfacing with CO₂ lasers represented in the past the gold standard for skin rejuvenation. This method is nevertheless associated with long recovery times, persistent erythema and a certain risk of side effects especially for darker skin types.

For this reason the “fractional ablative resurfacing” is therefore the method of election for treating patients requiring short recovery times, with partial restructuring of the epidermis and shrinking of tissue and new collagen formation, but with reduced effects compared to traditional resurfacing. In fact, the use of scanning systems which generate thermal effects in micro-areas (20%) surrounded by healthy tissue, allows for faster recovery with persistent erythema only lasting 3-7 days. The rapid re-epithelization on the second day enables restoration of the epidermal barrier, making it possible for patients to resume their normal social activities.

Fractional resurfacing usually requires several sessions, which are well-tolerated by the patient thanks to the immediate clinical result (shrinkage) and short convalescence after each session (minimal down-time).

When combined with traditional resurfacing, the fractional resurfacing techniques thus introduce a new working strategy that allows for identifying the most appropriate laser treatment according to the severity of the photodamage, and meets patients' demands for always shorter recovery times.

1.3 Scars

Scarring is the most important long-term complication of burn injuries or trauma on the skin. A scar is the body's natural way of healing and replacing lost or damaged skin. A scar is usually composed of fibrous tissue. Scars may appear anywhere on the body, and the composition of a scar may vary. A scar may appear flat, lumpy, sunken, or colored. It may be painful or itchy. The final look of a scar depends on many factors, including the skin type and location on the body, the direction of the wound, the type of injury, age of the person with the scar, and his or her nutritional status. Scars usually fade over time. Makeup can help cover the scar while it is healing. Some scars can be minimized by certain dermatological techniques (i.e. Dermabrasion, Chemical peels, Cortisone injections, etc.).

Traditional resurfacing with CO₂ laser is highly effective in treating scars. However, a really long down-time and high incidence of adverse effects has limited its use in routine dermatology practice. Fractional CO₂ laser resurfacing circumvents many of the above-mentioned disadvantages of traditional laser resurfacing.

With the fractional treatment, only a fraction of the whole skin is treated in a pixelated pattern while the intervening skin remains intact. This allows the treating physicians to go for much deeper treatment than with traditional laser resurfacing. Additionally, the adverse effects encountered with fractional technique are transient and less severe than with full skin resurfacing. Fractional CO₂ laser resurfacing has been successfully used in the treatment of atrophic acne scars, hypertrophic as well as burn scars.

2

Technical Features

2.1 General System Specifications

TETRA PRO (Suggested Configuration in Dermatology and Aesthetic Medicine)	
Laser Source	CO ₂ RF-PSD
Wavelength	10600 nm
Range Power at handpiece Output	0.1 W - 40 W
Operating Modes	CW-SP-DP-HP-UP
General features	
Internal Database	More than 100 factory stored protocols, upgradeable with USB. Possibility for the user to store a number unlimited custom protocols
Control Panel	Colour LCD Touch Screen
Accessories	DOT PRO, Scar 3 PRO, V ² LR PRO, Dermascan and wide range of handpieces
Dimensions and weight	124 (H) cm x 64 (W) cm x 66 (D) cm 62 Kg

Applications (for the suggested configuration in dermatology and aesthetic medicine):

- incision, excision, ablation, vaporization and coagulation of body soft tissue, in dermatology and plastic surgery.



2.2 Tetra Pro System in Brief

The Tetra PRO system is a 10600 nm Carbon Dioxide (CO₂) laser device delivering a maximum power of 40 W. It is well known that the 10,600 nm wavelength is mostly absorbed by water; this characteristic makes it particularly suitable for soft tissue surgery. CO₂ laser surgery is recognized as being minimally invasive and highly effective, as proven by hundreds of scientific published articles over the last twenty years regarding surgery and microsurgery with this type of laser in various disciplines.

The systems may be used in combination with a new family of high-tech, ergonomic scanners in order to achieve a greater treatment predictability and reproducibility:

- DOT PRO and Scar 3 PRO: These scanning units are indicated for layer-by-layer char-free ablation, enhancing the safety of the treatment with more uniform, accurate and controllable impact such as ablative and fractional treatment.
- The DermaSCAN is a microscanner used with handpieces only and is specially optimized for dermatological surgery applications (scanner-assisted vaporizations).
- The V²LR PRO (designed for vulvo-vaginal laser applications) complete the range of scanners available for medical applications in fields other than dermatology and aesthetic medicine.

(More details and indications for the use of these scanners are given in the Tetra PRO system operating manual and in the specific clinical manuals for the branches of competence.

This clinical manual is exclusively dedicated to the use of the system and its accessories in dermatology and aesthetic medicine).

2.2.1 Pulse Shapes

The aim of the system is to generate perfectly-controlled energy pulses, making it the ideal solution for skin resurfacing treatments and skin surgery. The technology eliminates the side effects of constant scanning and is always active, during both the traditional and fractional scanning phases and during the use of handpieces.

With special pulse mode the system can allow two different effect to the tissue:

- **Ablation:** The high power peak of the pulse releases a large quantity of energy in a very short time, for rapid ablation of the epidermis and the first layers of the derma with a lower water content.
- **Thermal effect:** After this rapid vaporization, the energy of the pulse spreads the heat in the water-rich deep derma, generating immediate shrinkage and the production of new collagen. The damage to the epidermis is minimal and recovery times are dramatically reduced.

TECHNICAL FEATURES

The emission modes developed thanks to advanced software and laser source management (PSD® Technology), such as S-pulse, H-pulse, and D-pulse, allow for achieving:

- Different spatial heat distribution patterns;
- Different ablation area shapes;
- Different lateral heat damage distribution;
- Different tissue shrinkage profiles.

Thanks to this technology and the range of available pulse modes, different biological effects can be induced on the tissue stimulating the dermis to produce new collagen, naturally regenerate the tissue structure, and improve skin tightening or softness.

More in detail, the S-pulse mode acts more selectively on the papillary dermis with a more circular ablation shape, inducing coagulation of the surrounding tissues.

The D-pulse mode acts more incisively on the reticular dermis, inducing greater shrinkage of the ablation columns and more circumscribed coagulation; it is therefore particularly indicated in the treatment of flabby skin when used with the scanner.

Confocal laser microscopy assessment and histological studies reveal the special “funnel-shaped” ablative shape achieved in the D-pulse mode, which is different to the one obtained with S-Pulse technology. The former mode allows for greater shrinkage than with the S-Pulse technology. Histological studies of the D-Pulse ablation show a depression of the portion of epidermis not involved in the hardening phenomenon caused by the wave of immediate heat. This can be ascribed to the deeper action exerted by this mode, which, by also entailing the reticular dermis, induces greater shrinkage in a vertical direction as well. A third emission mode, called H-pulse, is also available for scars treatment using the Scan Scar 3 PRO scanning unit and for vaporizing skin lesions, especially when used in freehand mode.

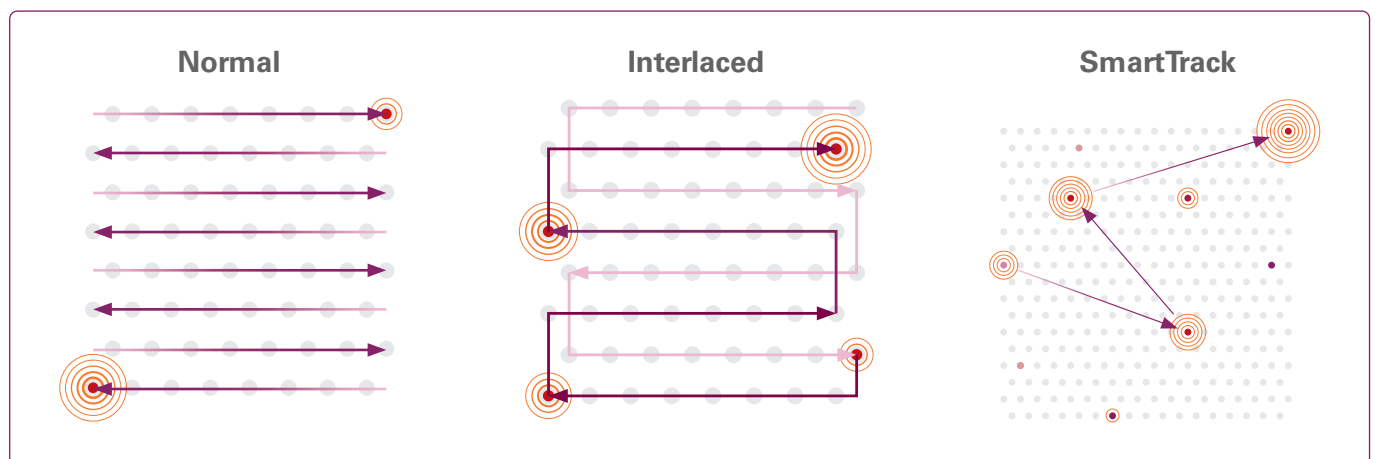
Thanks to its higher emission power than the S-Pulse and D-Pulse modes described above, H-pulse also makes it possible to obtain two additional effects on the tissues:

- it can be used for cold, more delicate ablation thanks to the very low pulse emission times,
- and for carrying out greater ablation than the other emission modes applied for the same pulse duration.

2.2.2 Scanning Modes

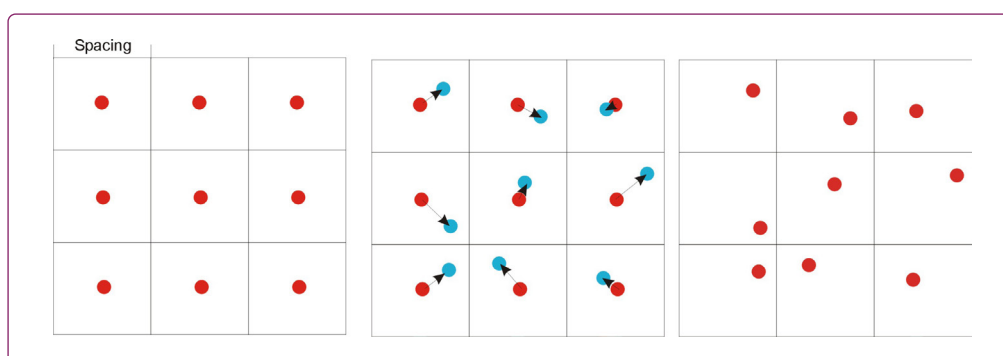
It is possible to choose among three different scan modes:

- **Normal scan mode:** The area is treated by scanning lines from left to right and from right to left, starting from the first line at the top, to the last line on the bottom.
- **Interlaced scan mode:** The area is treated by scanning the odd numbered lines first, followed by the even numbered lines. Once the odd numbered lines have been scanned from the top to the bottom, the even lines are scanned from the bottom to the top. Use of the interlaced scan mode is advisable for reducing thermal effects during treatment.
- **SmartTrack scan mode:** The area is treated by scanning dots in random order. Developed to enhance post-treatment recovery, this scanning mode minimizes the risk of tissue overheating, and therefore thermal damage. (This scan mode is not available with the "CW" option).



2.2.3 Scattered Mode

By pressing the "☼" icon in the Scan Pattern menu, it is possible to activate the **Spray mode**. When this mode is active, the dots are spaced in a special random way, avoiding overlapping. With "Spray Mode", the fading out at the borders and the pseudo-random covering of the scanning area provide a more uniform transitions between contiguous areas and more homogeneous DOT textures.



TECHNICAL FEATURES

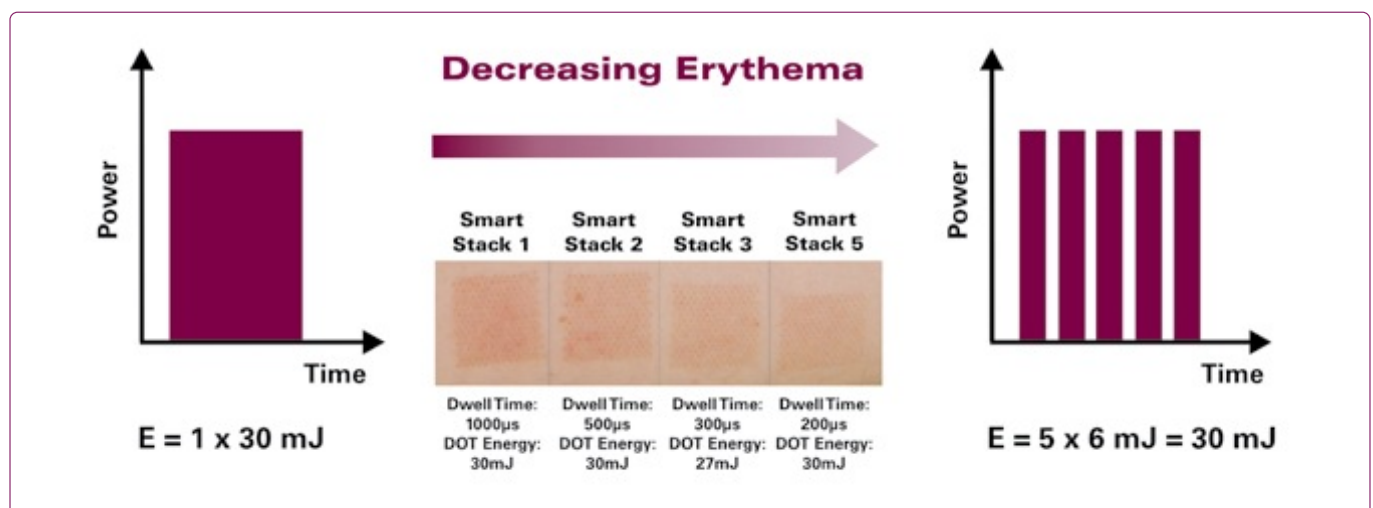
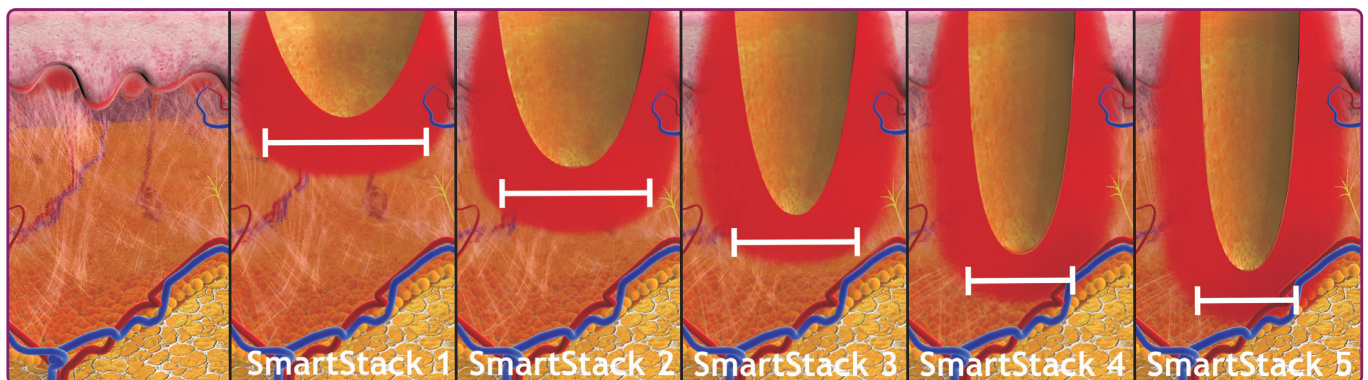
2.2.4 Stack Theory

SmartStack is an important feature present in the Tetra PRO system for ensuring even better results and greater flexibility. Selecting and editing the SmartStack parameter it is possible to manage the number of pulses (for a maximum of 5 times) delivered consecutively by the system on the same “dot” before moving on to the next one.

SmartStack can be used in two almost contrasting modes.

The first operating mode uses high powers, producing deep ablation but always with a significant thermal effect around the vaporized area.

The second mode is even more innovative as it introduces a “temporal” as well as a spatial fractioning of the energy. Instead of using all the energy in a single pulse it is more beneficial to fraction it over time, while still releasing the same total energy. The sub-pulses fractioned in this way allow the skin to cool down, guaranteeing reduced erythema without compromising the “tightening” effect. The following figure gives a better idea of the temporal fractioning effect produced by the SmartStack system.



As illustrated in the figure, erythema appears less evident with SmartStack=5 compared to 1 single pulse (SmartStack=1) or lower SmartStacks.

The use of fractioned lasers (in spatial mode only) has considerably reduced the side effects produced by the high concentrations of laser energy that overheated the dermis.

All efforts made so far have focused on achieving a good “tightening” effect, reducing to a minimum the side effects, the main component of which is erythema.

By selecting the parameters available in the Tetra PRO system (Power, Dwell Time, Spacing and SmartStack level) it is now possible to assess the “degree of erythema” and the “tightening” effect at first glance. By bearing these parameters in mind therefore, it is possible to balance the treatment according to the desired results and downtime.

NOTE: In theory, this scanning mode (i.e. Stack 3) should have the same effect on tissues as 3 consecutive scanning applications, however it has the advantage of ensuring greater overlapping by emitting three pulses over the same dot.

2.3 Tetra PRO Scanners

Tetra PRO has a range equipped with new scanning systems, optimized in shape, weight, easier connection and size to maximize handling.

2.3.1 DOT PRO scanner

Scanning system designed to ensure utmost ergonomics in fractionated or traditional resurfacing treatments.

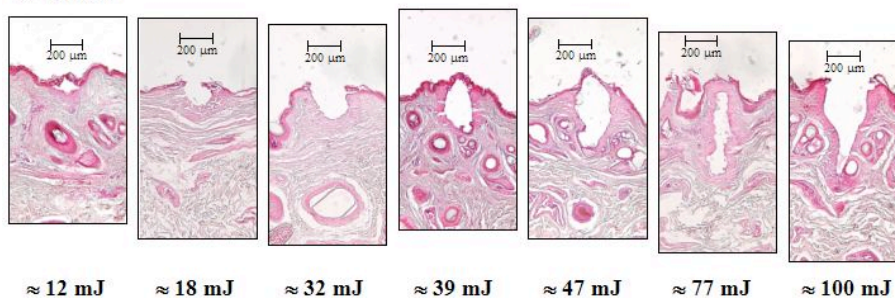
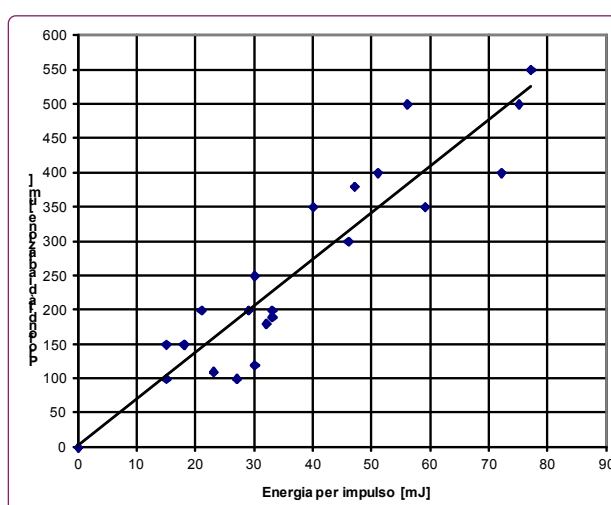
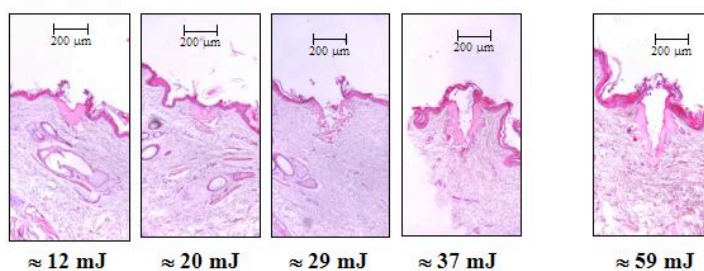
Focal Length	100 mm
Scanning Area (max)	20 mm x 20 mm
Emission Modes	CW-SP-DP-HP-Moveo
Output Power in SP - DP - HP - CW Emission Modes	0.5- 40 W
Scanning Area Shapes	DOT, Line, Triangle, Ellipse, Hexagon, Square, Annular Ring
Scanning Modes	Normal, Interlaced, SmartTrack
Dwell Time	0.1 – 45 ms
Spacing	0 -2 mm (Spacing is not selectable in “CW” mode)
Smart Stack	From 1 to 5 (Smart Stack is not available in “CW” mode)



TECHNICAL FEATURES

The depth of ablation is typically correlated to the "Energy per DOT". According to the histological test, a formula could be evaluated. The actual values could vary due to different kind of tissues, but should be used to have an estimation of the intensity of the treatment with a tolerance of 70 μm .

$$\text{"Ablation depth" } [\mu\text{m}] = 6 \times \text{"Energy per pulse" } [\text{mJ}]$$

S-Pulse**D-Pulse**

2.3.2 Scar 3 PRO scanner

Scanning system designed for remodelling deep scars. Minimizes the risk of post-treatment hyper and hypopigmentation thanks to the smaller spot size that generates greater depth of the action with reduced energy.

Focal Length	75 mm
Scanning Area (Max)	15 mm x 15 mm
Emission Modes	CW-SP-DP-HP-Moveo
Output Power in SP - DP - HP - CW Emission Modes	0.5 - 40 W
Scanning Area Shapes	Dot, Line, Triangle, Ellipse, Hexagon, Square, Annular Ring
Scanning Modes	Normal, Interlaced, Smarttrack
Dwell Time	0.1 – 45 mm
Spacing	0 -2 mm (Spacing Is Not Selectable In "CW" Mode)
Smart Stack	From 1 To 5 (Smart Stack is not Available In "CW" Mode)



The Scar 3 PRO scanner is used for a minimally invasive laser procedure of thickened scars of any severity, including deep contracted lesions, and complex skin lesions, anytime a very accurate, deep fractional treatment is required.

Scar 3 PRO works by delivering high laser energy deep into the skin to break up existing scar tissue and promote normal collagen regrowth. It substantially improves either the structure of deep contracted skin lesions leading to reacquire some motion on all the areas affected and skin appearance. This treatment can reduce differences in tissue makeup and pigmentation relative to the surrounding normal skin, diminishing the appearance of the scar.

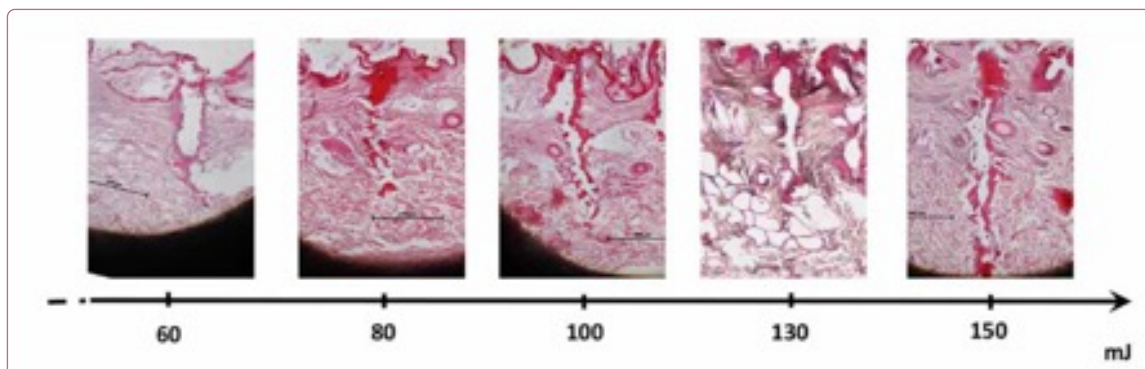
What is the main difference between Scar 3 PRO and DOT PRO scanners?

Scar 3 PRO is able to penetrate deeper into the skin compared to the typical penetration of DOT PRO laser emission. This enables Scar 3 PRO to address even extremely thick forms of scarring.

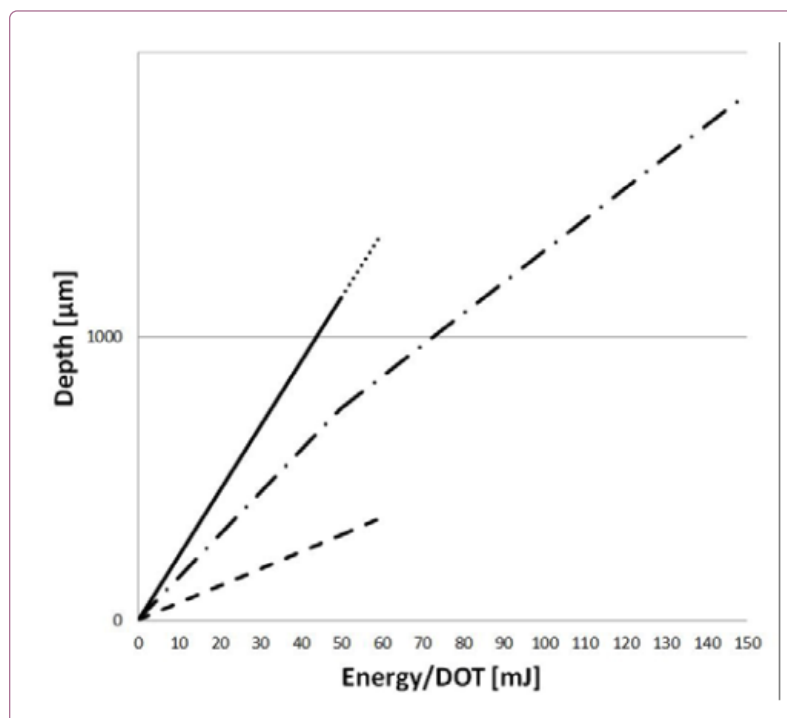
According to the histological test, also with the SCAR 3 scanner system a formula could be evaluated. As for the DOT PRO, the actual values could vary due to different kind of tissues, but should be used to have an estimation of the intensity of the treatment with a tolerance of 100-150 µm.

TECHNICAL FEATURES

$$\text{"Ablation depth" } [\mu\text{m}] = 12 \times \text{"Energy per pulse" } [\text{mJ}]$$



In the graph below, it is shown the plot of the depth as the energy increase: the Thermal Lesion Depth achieved with Scar 3 PRO scanner (continuous line); the Ablation Depth achieved with Scar 3 PRO scanner (dash-dot line); the Ablation Depth reported in literature data for DOT scanner (dashed line).



Finally Scar 3 PRO scanner is also extremely customizable, enabling operators to adapt the treatment to meet the individual needs of each patient's scar type. By varying the impulse modality on the on the area concerned it's possible to obtain different ablation and stimulation effects to meet the various clinical needs.

Another advantage of Scar 3 PRO scanner is due to its possible use for tattoo removal since its effectiveness has been observed when combined with fractional Q-switch laser.

2.3.3 DermaSCAN

This scanning system was developed for surgical dermatology treatments to enhance vaporization capability of standard freehand handpieces. It is paired with handpieces with 4" and 7" focus designed for fast and tridimensional ablations.

Scanning Area (Max @400 mm Focal Length)	6.3 mm x 6.3 mm
Emission Modes	CW-HP
Scanning Shapes	Cut Mode (Point), Ellipsoid Motion on a Circular Surface, Filled Hexagon, Hexagon DOT, Filled Circle
Output Power	From 0.5 W to 40 W
Dwell Time	From 100 μ s to 45 ms



This new scanner allows to take advantage of the following scan figures: circle, "cue ball", hexagon and point.



The "cue ball" figure allows to perform an ultra-fast ablation while the full geometric figures (as circle and hexagon) allow to have a 3D ablation with maximum and precise depth control.

3

Clinical Procedure

3.1 General Guidelines

This manual provides information on how to use the system but it cannot replace the physician's clinical judgement. General rule is to preserve the skin. The higher levels of power and energy must be selected with extreme caution in order to prevent damage to the skin.

The user must keep note and be familiar with each type of treatment before proceeding with setting the parameters. As with any dermato-surgical modality, the doctor must have a complete understanding of the indication and limitation of a given laser procedure.

The information contained in this manual has to be considered as a suggested use of the device. It cannot be considered an exhaustive and comprehensive guide for the use of Tetra PRO device and cannot in anyway substitute for operator experience and observation.

DEKA recommends that all qualified personnel who operate the system first seek training that includes, but is not limited to, the following aspects:

Training for this device is provided by DEKA M.E.L.A srl or people authorized by DEKA M.E.L.A srl.

NOTE: For more detailed indications about “how to use the system” and “safety recommendations” please refer to the Tetra PRO Operator’s Manual received with the system.

3.2 Clinical Benefits

The majority of the patients treated show a complete remission of the lesions or a partial remission. In fact, patient satisfaction is very high (most of the scores ranged between “excellent and good results”).

Moreover, some articles showed an improvement of collagen homogenization in patients treated with this type of device.

3.3 Pre-Treatment Care

First and foremost, it is important for the professional to carry out an examination and anamnesis of the patient in order to select the most appropriate treatment. Anamnesis makes it possible to discover any illnesses, risk factors and possible causes in the patient's history that might compromise overall treatment outcome. The main information to take into account for drawing up the most suitable treatment plan includes:

- Patient's medical and family history (we suggest to investigate about any history of hypersensitive to the light; seizure disorders triggered by light; autoimmune disorders or any immunosuppression; blood disorders; a personal or family history of skin cancer; active infections - bacterial, viral or mycotic - in progress; a personal history of skin disorders or other medical conditions that significantly compromise the healing response; any other illness, use of injectables/fillers and/or precedent thread lift). Usually, resorbable fillers do not interact with this wavelength. However, it is recommended to carry out the laser treatment earlier than the filler injection so that the laser can better prepare the skin to receive the filler. Given the variety of traction threads, different depths, types of resorptions and variability of distribution, it is advisable to consult the manufacturer of traction threads before proceeding with treatment.
- Type of lesion to be treated (size, depth, location, colour, severity)
- Phototype
- Patient's age
- Patient's motivations and expectations
- Recent sun exposure.
- The patient must be suitably informed about:
 - The treatment procedure (Illustrate the active principle of the laser and the treatment method),
 - The results that he can expect according to his individual characteristic,
 - The probable number of sessions necessary for achieving the desired results (it will vary according to the characteristics of the subject),
 - The steps to follow before and after each treatment session and any possible side effects,
 - Illustrate the typical immediate skin reaction after treatment.

3.3.2 Motivations and Expectations

During the patient's interview and inspection, detailed information has to be collected not only in relation to the symptomatology but also about motivations and goals that have made the patient contacting the medical or aesthetics centre.

3.3.3 Target Population

The Tetra PRO device can be used on all patients that need the treatments described in the intended use with the exception of those contraindicated. There are not gender or age restrictions for the target population.

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3.3.4 Contraindications and Precautions

The treatment is contraindicated for patients who have recently undergone an exfoliation treatment, surgical treatments such as lifting and any patient with past skin disorders, including keloids.

After the preliminary interview with the patient, the physician will judge whether it is appropriate to perform the treatment, or even to postpone or exclude altogether.

Following is a list of several conditions which according to their specific anatomical site, severity and specific features pertaining to each case, could be a reason for particular precaution or excluding a patient wishing to the treatment.

- Sun and UV lamp exposure: avoid prior to (at least 1 month), during and after treatment. Apply SPF50 sunblock before and after the treatment.
- Be careful in case the patient is taking following types of drugs (suspend the administration according to the specific drug so that its effect is expired before the treatment):
 - Anticoagulants (as acetylsalicylic acid, heparin, etc.). These drugs can cause persistent erythema.
 - Retinoids (as isotretinoin, etc). These drugs can cause problems in the healing process with possible scar results.
 - Photo-sensitizers (as tetracycline [antibiotic], naproxen [NSAD], auranofin [antirheumatic], oestrogens and progestins [oral contraceptive], cloroquine [antimalarial], etc.)
 - Immunosuppressant
 - Corticosteroids
- Subjects with a history of Herpes may be prescribed antiviral prophylaxis some days before the treatment.
- Pregnancy and breastfeeding patients
- Subjects with dark phototypes (III-VI) should follow a pre-operative protocol to help prevent post inflammatory hyperpigmentation (PIH), beginning a few days prior to treatment.
- The doctor, based on the treatment results, may consider prescribing antibiotic drugs.
- Before starting the treatment, it is necessary to perform a skin test on a small area so that the doctor can evaluate the skin reaction and possibly adjust the parameters.

3.3.5 PIH Prevention

In order to ensure a positive outcome with laser treatment, the patient must strictly follow a pre-operative protocol to help prevent possible complications.

Especially with darker phototypes (III, IV, V and VI) and Asian phototypes, it is recommended to apply a topical cream every day for four weeks before the treatment for inhibiting melanin production. It is possible to use cream containing hydroquinone or, as alternative lighteners, arbutin, azelaic acid, kojic acid or stabilized vitamin C. This procedure is highly recommended with darker and Asian skin types, while for photo type I and II it is just a suggestion.

3.3.6 Infection Prevention

In order to ensure a positive outcome with laser treatment, the patient must strictly follow a pre-operative protocol to help prevent possible complications.

The drugs used fall into two main categories:

- **Antiviral drugs** (aciclovir, valaciclovir, etc). It is suggested to start the antiviral prophylaxis 6 days before the treatment in subjects with a positive anamnesis of herpes virus infections history. The antiviral treatment can start 2 days before the treatment in subjects without previous experience of herpes infections. It is recommended to continue the antiviral drugs at routine doses for 5-15 days after the intervention.
- **Antibiotic drugs** (macrolides, cephalosporins, etc). The doctor may consider prescribing antibiotic drugs for 7-8 days after the procedure. Remark: It is not necessary to prescribe antibiotic drugs in all cases. It is often enough the application of a topical antibiotic cream or ointment (like gentamicin) after the procedure.

The doctor, based on the treatment results, may consider prescribing antiviral or antibiotic drugs.

3.3.7 Side Effects

For dermatological application side effects could be mild to moderate pain during the treatment, burning sensation, bleeding and mild to moderate posttreatment erythema, itching, crusting and oedema that resolve in few days.

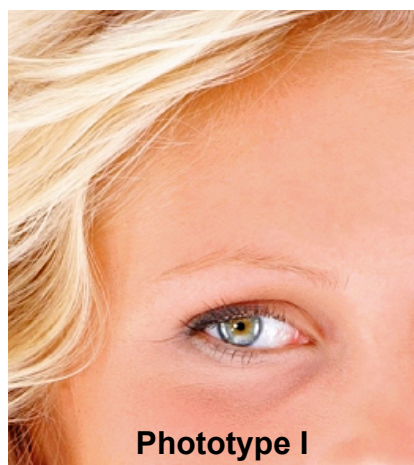
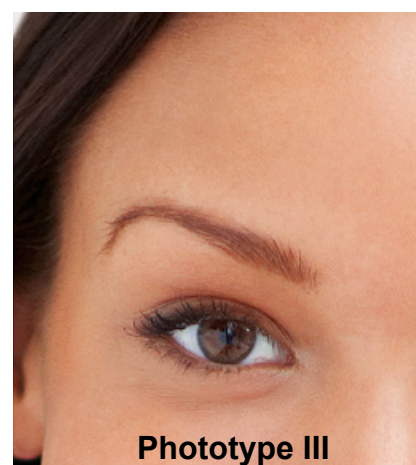
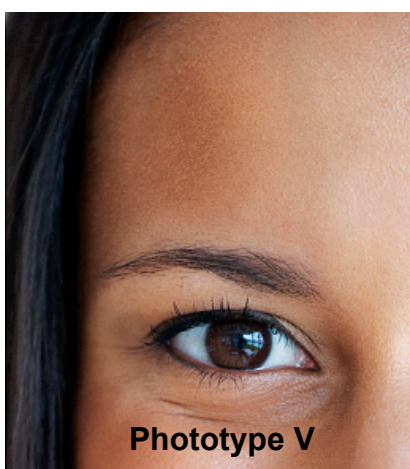
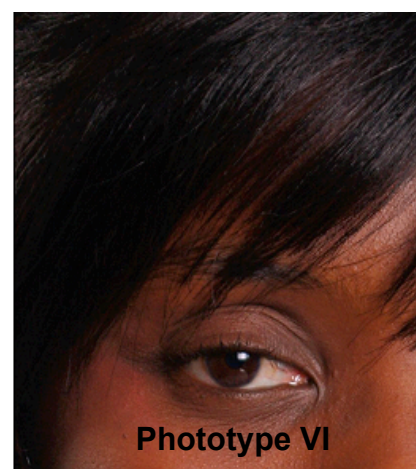
Adverse effect such as prolonged hyper/hypo pigmentation, scars and burn may result from improper use or excessive energy.

3.3.8 Classification of the Phototypes

Before starting treatment it will be necessary to evaluate the patient's phototype to evaluate any possible risk or side effects.

Type	Hair colour	Skin colour	Eye colour	Reaction to the sun
I	Red	Fair	Blue-grey	Goes red, does not tan
II	Blonde	Fair	Blue	Goes red, does not tan
III	Brown	Medium	Brown	Goes red, then tans
IV	Dark Brown	Light brown	Dark brown	Tans
V	Black	Dark brown	Black	Tans
VI	Black	Black	Black	Tans

CLINICAL PROCEDURE

**Phototype I****Phototype II****Phototype III****Phototype IV****Phototype V****Phototype VI**

3.3.9 Cleaning the Skin

Before treatment clean the relevant area, removing all impurities that could interact with the light radiation (make-up, lotions, deodorants, ointments etc.). Use a mild soap and rinse well with water. As a precaution the patient should be advised not to use cosmetics for 48 hours prior to treatment.

3.3.10 Photographic Monitoring

Taking pictures that document the patient during the various treatment phases helps to monitor the effectiveness of the treatment. For ensuring the best photographic quality it is necessary to standardize the shots in order to reproduce the same position of the patient and the same lighting conditions.

3.3.11 Anaesthesia Indications

Dermal treatments with laser may give rise to a painful sensation described as similar to an elastic band being pinged against the skin, or the pain caused by burns.

The anaesthetic protection for CO₂ laser skin therapies becomes necessary in specific cases, such as:

- Traditional CO₂ laser skin resurfacing;
- The treatment of extensive skin areas;
- The treatment of deep lesions;
- Patients with a low pain threshold;
- Non-compliant patients;
- Paediatric patients.

Irrespective of the anaesthetic method used (such as transdermal and infiltrative anaesthesia or peripheral and loco regional blocks), several indispensable precautions are necessary. A careful clinical assessment (if an anaesthetist is necessary this will be their exclusive responsibility), with particular attention to cardiovascular, pulmonary, and neurological pathologies, hypertension, diabetes, allergic phenomena and/or any idiosyncratic reactions to the medicinal products to be administered;

Detailed indications regarding the administration, modification or discontinuation of therapies in progress (in the current condition and in relation to the type of intervention/treatment, the assessment will mainly concern the anticoagulant therapy).

In case of fractional resurfacing with CO₂ Tetra PRO emission, it is usually enough to apply a topical anaesthetic 1 hour before the treatment. In case of quite superficial action, to use the SmartCryo skin cooling system during the treatment can be a possible alternative to the topical anaesthetic.

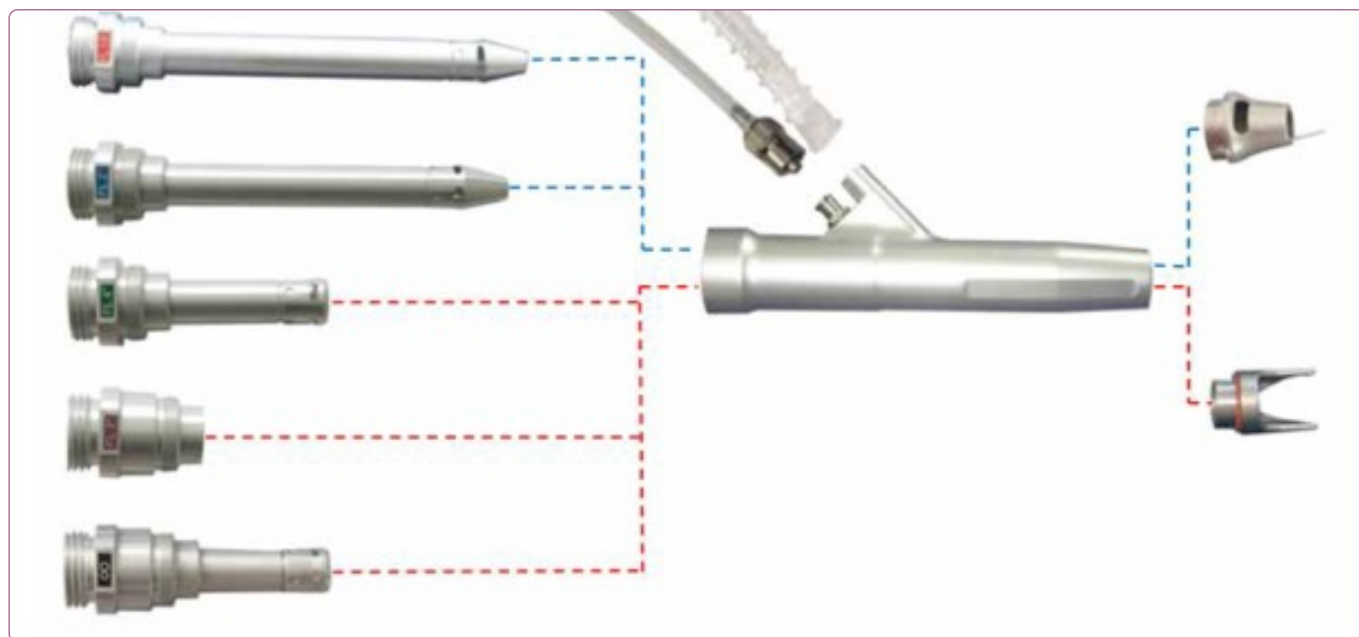
The use of anaesthetic protection could influence the correct perception of the pain during the treatment and the adverse effects.

CLINICAL PROCEDURE

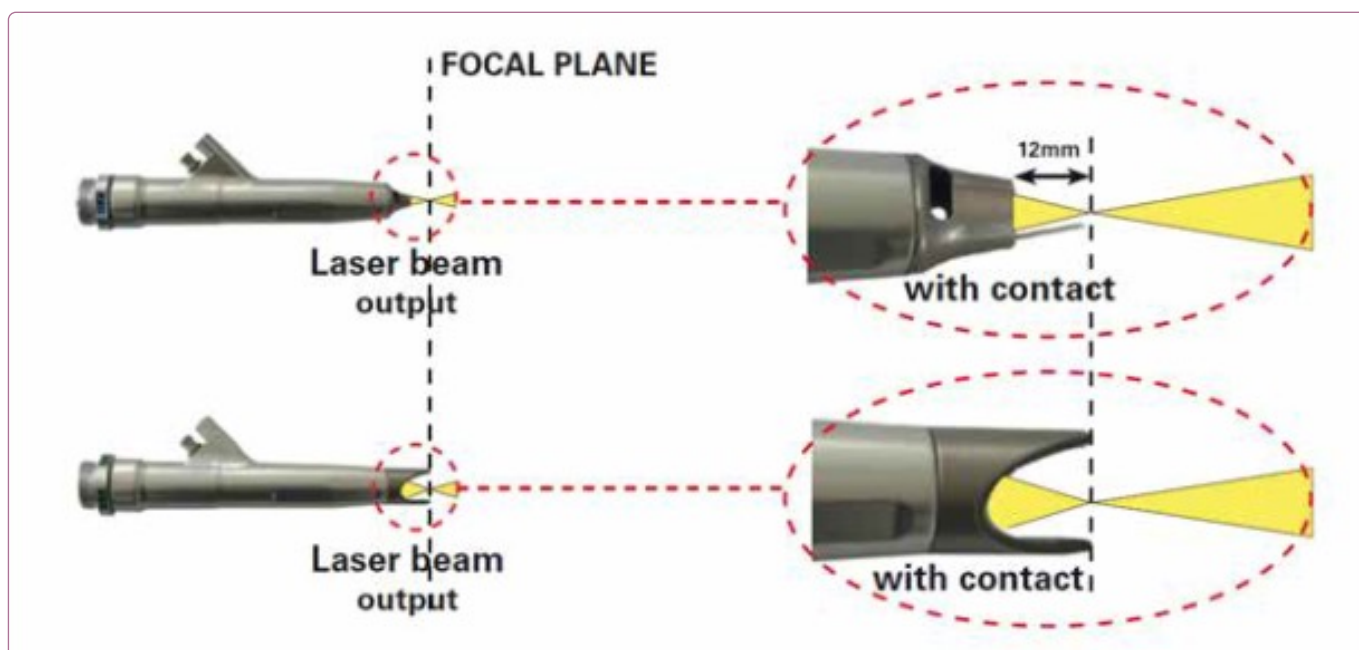
3.4 Skin Surgery Procedures - Free Hand

A wide range of handpieces are available for the Tetra PRO system, with different spot sizes and high performance in specific fields of application.

The system can be equipped with a handpiece body housing different lens assemblies (1.5", 2", 4", 7" and collimated).



The term "spot size" refers the diameter of the laser beam (and therefore the diameter of the circular area exposed to laser radiation) when the handpiece is held perpendicular to the surface being treated and the laser beam is in the focal point.



The suggested value should be fit with the dimension a depth of the lesion. The operator must be skilled in determining the best level of power to be used that will vary during the ablative treatment.

The higher level represents the higher ablation rate. We suggest to start with the lower indicated level to be used as starting point for being able to increase the work power in order to achieve the requested ablation and greater benefits, while monitoring the side effects, tolerability and depth of the lesion.

Consider that usually, after the detection of the best starting value, the procedure starts setting with high level value (which corresponds to a deeper skin ablation effect) for the "rough-shape" phase. At the end of the procedure the level value is reduced to perform more precise "final touches". In particular we suggest to start with a SP mode, that represent the typical CO2 ablation, and finally use the HP mode to obtain a more precise finishing of the lesion with a "cold Er:YAG laser like" effect.

The following settings are developed by the use of the 7" or the collimated handpiece.

NOTE: **Slightly defocused** means approximately 2-3 mm far from the skin; Defocused means approximately 5 mm far from the skin.

Treatments	Emission Mode	Power (W)	Frequency (Hz)	Handpiece	Distance to the tissue*
Sebaceous adenoma	SP	0,5/1	10/20	7"/collimated	Focalised or slightly defocused
Seborrheic keratosis d <0,5 cm	HP	0,1/0,8	5/10	7"/collimated	Focalised or slightly defocused
Seborrheic keratosis d >0,5 cm	DP	0,1/2	10/20	7"/collimated	Focalised or slightly defocused
	CW	7		7"/collimated	Defocused
Actinic keratosis	SP	0,1/1	10/20	7"/collimated	Slightly defocused
Actinic cheilitis	SP	0,1/1.5	10/20	7"/collimated	Focalised or slightly defocused
Acne scars	HP	0,1/0,5	5/10	7"/collimated	Focalised or slightly defocused
Condyloma Acuminatum	SP	0,5/2	10/20	7"/collimated	Focalised or slightly defocused
	CW	4/10W		7"/collimated	Defocused
Chondrodermatitis nodularis helices	SP	0,1/1	10/20	7"/collimated	Slightly defocused
Molluscum fibroma	HP	0,1/0,4	5/10	7"/collimated	Focalised
Apocrine hidrocystoma	SP	0,1/0,7	10	7"/collimated	Focalised or slightly defocused
Hirsuties papillaris genitalis	SP	0,1/0,5	10/20	7"/collimated	Focalised or slightly defocused
Superficial Dyschromias	HP	0,1/0,3	5/20	7"/collimated	Slightly defocused
Leukoplakia (with biopsy)	SP	0,1/1,5	10/20	7"/collimated	Focalised or slightly defocused

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Treatments	Emission Mode	Power (W)	Frequency (Hz)	Handpiece	Distance to the tissue*
Favre-Racouchot's disease	SP	0,1/0,7	10/20	7"/collimated	Focalised or slightly defocused
Milium	HP	0,1/0,3	5/10	7"/collimated	Focalised
Pringle Bourneville's disease	HP	0,3/0,9	5/10	7"/collimated	Slightly defocused
Sebaceous Nevus	SP	0,3/0,7	10	7"/collimated	Slightly defocused
Neurofibroma	HP	0,1/1	5/10	7"/collimated	Focalised or slightly defocused
Dermal Nevus (with biopsy)	SP	0,1/1,5	10/20	7"/collimated	Focalised or slightly defocused
Epidermal Nevus	SP	0,1/1	10/20	7"/collimated	Focalised or slightly defocused
Otophyma	SP	0,3/1,5	10/20	7"/collimated	Focalised or slightly defocused
Oral papilloma	SP	1/1,5	20	7"/collimated	Focalised or slightly defocused
Glandular rhinophyma	SP	0,9/3	10/20	7"/collimated	Focalised or slightly defocused
	CW	5/8W		7"/collimated	Defocused
Syringoma	HP	0,1/1	5/10	7"/collimated	Focalised or slightly defocused
Trichoepithelioma	SP	0,1/1,5	10/20	7"/collimated	Focalised or slightly defocused
Common wart	SP	0,3/2	10/20	7"/collimated	Focalised or slightly defocused
	CW	3/4 W		7"/collimated	Defocused
Flat wart	HP	0,1/0,7	5/10	7"/collimated	Focalised or slightly defocused
Filiform wart	HP	0,1/0,7	5/10	7"/collimated	Focalised or slightly defocused
Plantar wart	CW	3/5 W		7"/collimated	Defocused
Xanthelasma	HP	0,1/1	5/10	7"/collimated	Defocused

The following settings are developed by the use of the 4" Handpiece.

4" free hand handpieces must be used for vaporization in a defocused manner, slightly distancing them from the skin.

NOTE: Slightly defocused means approximately 2-3 mm far from the skin; Defocused means approximately 5 mm far from the skin.

Treatments	Emission Mode	Power (W)	Frequency (Hz)	Handpiece	Distance to the tissue
Sebaceous adenoma	SP	0,5/1	10/20	4"	Slightly defocused
Seborrheic keratosis d <0,5 cm	HP	0,1/0,8	5/10	4"	Slightly defocused
Seborrheic keratosis d >0,5 cm	DP	0,1/2	10/20	4"	Slightly defocused
	CW	7		4"	Defocused
Actinic keratosis	SP	0,1/1	10/20	4"	Slightly defocused
Actinic cheilitis	SP	0,1/1.5	10/20	4"	Slightly defocused
Acne scars	HP	0,1/0,5	5/10	4"	Slightly defocused
Condyloma Acuminatum	SP	0,5/2	10/20	4"	Slightly defocused
	CW	4/10W		4"	Defocused
Chondrodermatitis nodularis helices	SP	0,1/1	10/20	4"	Slightly defocused
Molluscum fibroma	HP	0,1/0,4	5/10	4"	Slightly defocused
Apocrine hidrocystoma	SP	0,1/0,7	10	4"	Slightly defocused
Hirsuties papillaris genitalis	SP	0,1/0,5	10/20	4"	Slightly defocused
Superficial Dyschromias	HP	0,1/0,3	5/20	4"	Slightly defocused
Leukoplakia (with biopsy)	SP	0,1/1,5	10/20	4"	Slightly defocused
Favre-Racouchot's disease	SP	0,1/0,7	10/20	4"	Slightly defocused
Milium	HP	0,1/0,3	5/10	4"	Slightly defocused
Pringle Bourneville's disease	HP	0,3/0,9	5/10	4"	Slightly defocused
Sebaceous Nevus	SP	0,3/0,7	10	4"	Slightly defocused
Neurofibroma	HP	0,1/1	5/10	4"	Slightly defocused
Dermal Nevus (with biopsy)	SP	0,1/1,5	10/20	4"	Slightly defocused
Epidermal Nevus	SP	0,1/1	10/20	4"	Slightly defocused

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Treatments	Emission Mode	Power (W)	Frequency (Hz)	Handpiece	Distance to the tissue
Otophyma	SP	0,3/1,5	10/20	4"	Slightly defocused
Oral papilloma	SP	1/1,5	20	4"	Slightly defocused
Glandular rhinophyma	SP	0,9/3	10/20	4"	Slightly defocused
	CW	5/8W		4"	Defocused
Syringoma	HP	0,1/1	5/10	4"	Slightly defocused
Trichoepithelioma	SP	0,1/1,5	10/20	4"	Slightly defocused
Common wart	SP	0,3/2	10/20	4"	Slightly defocused
	CW	3/4 W		4"	Defocused
Flat wart	HP	0,1/0,7	5/10	4"	Slightly defocused
Filiform wart	HP	0,1/0,7	5/10	4"	Slightly defocused
Plantar wart	CW	3/5 W		4"	Defocused
Xanthelasma	HP	0,1/1	5/10	4"	Defocused

1.5" and 2" handpieces are suggested for cutting procedures. The following settings are developed for laser cut:

Treatments	Emission Mode	Power (W)	Frequency (Hz)	Handpiece	Distance to the tissue
Cold Cut	HP	2-4	50	1.5", 2"	Focalised
Coagulation Cut	DP	2-4	50	1.5", 2"	Focalised

3.5 Skin Surgery Procedures - DermaSCAN

DermaSCAN unit can be used with long focal handpieces (4" as first choice or 7" possibly). For cutting tissue the 2" handpiece can be used.

To take full advantage of its performance (**3D-scan ablation**), it is recommended to use the DermaScan system in contact with the skin. The 4" handpiece, used in contact, has the laser focus point which corresponds to the contact point of the handpiece. This allows for a more intense and cold ablation. On the contrary the 7" handpiece, having a larger spot, has a more thermal action. For both handpieces, by focusing/defocusing, the thermal action component on the tissue can be varied.

The 7" focal length has a larger scanning area that gradually decreases passing to 4" and then to 2".

The use of the DermaSCAN system allows to speed up the ablation/vaporization procedures thanks to the specific HP and CW emission modes specially designed for this scanner. The frequency is set automatically by the system to optimize the ablative mode. It is therefore particularly useful for those dermatological surgery treatments where larger areas need to be removed. As indicated above this scanner allows to take advantage of the following scan figures: "cue ball", circle, hexagon and point:

- The selection of the **"cue ball"** scan figure is indicated to perform a **fast ablation** generally in the initial stages of dermatological procedures when it is necessary to remove larger volumes, typically setting the HP emission mode.
- The use of the full scan figures, such as the **circle** and the **hexagon**, allows instead to perform a more precise and targeted ablation with excellent control of the depth of action. This type of setting is therefore generally indicated in the finishing stages of the dermatological procedure, typically setting the CW emission mode.
- Finally, the selection of the **point** scan shape (no scanning movement, the scanner is operative but fixed on one point) allows you to use the freehand handpiece without having to remove the scanner and taking advantage of the HP and/or CW characteristics, specially suitable for the 3D ablation.

Suggested setting in the following table:

Scanning Shape	Emission Mode	Dwell Time	Power	Size	Exposure Mode	Suggested Use and Recommendations
Cue Ball	HP	0.2 ms	4-10 W	Variable depending on the lesion	Continuous (The exposure time is fully controlled by the operator acting on the footswitch: as long as the footswitch is kept pressed, the shutter is open, the laser emission occurs and the scanning unit repeats the selected pattern. For more detailed indications please refer to the Operator's System Manual)	3D-scan fast ablation. Initial stages of dermatological procedures. For the power setting start with the lowest level and then increase it once you become more confident with the procedure. Suggested focal handpiece: 4" or 7" Anaesthesia always recommended.

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Scanning Shape	Emission Mode	Dwell Time	Power	Size	Exposure Mode	Suggested Use and Recommendations
Circle and Hexagon	CW	0.1 ms for 4" focal Handpiece 0.2-0.3 for 7" focal handpiece	8-15 W	Variable depending on the lesion	Repeated with delay: 0.1-0.3 s (The system opens the shutter and performs scanning sequences, according to the set delay value, until footswitch is kept pressed. The shutter does not close until the footswitch is released. For more detailed indications please refer to the Operator's System Manual)	3D-scan ablation with optimal penetration depth control. The finishing stages of the dermatological procedure. For both the power and the delay settings, start with the lowest levels and then increase them once you become more confident with the procedure. Suggested focal handpiece: 4" or 7" Anaesthesia always recommended.
Point (No scanning movement) VAPORIZATION	HP	-	4 W (with anaesthesia) Or 0.5 - 1 W (without anaesthesia)	Variable depending on the lesion	When the "No Scan" mode is selected, footswitch works in continuous way.	Freehand for tissue vaporization. Distance to the tissue: Defocused or slightly defocused. Remind that when the "No Scan" mode is set it is necessary to manually move the laser beam in order to avoid dangerous overexposures. For the power setting start with the lowest level and then increase it once you become more confident with the procedure. Suggested focal handpiece: 4" or 7". Also 2" is possible.

Scanning Shape	Emission Mode	Dwell Time	Power	Size	Exposure Mode	Suggested Use and Recommendations
Point (No scanning Movement) CUT	HP	-	6-10 W (with anaesthesia)	-	When the "No Scan" mode is selected, footswitch works in continuous way.	Freehand for tissue vaporization. Distance to the tissue: Focused. Remind that when the "No Scan" mode is set it is necessary to manually move the laser beam in order to avoid dangerous overexposures. For the power setting start with the lowest level and then increase it once you become more confident with the procedure. Suggested focal handpiece: 2" or 4".

The Dwell time is the length of time that the laser beam remains on a scanning point and, therefore, an increase in this parameter causes an increase in the ablative power and thermal power of the laser.

NOTE: **Slightly defocused** means approximately 2-3 mm far from the skin; **Defocused** means approximately 5 mm far from the skin.

REMARK: Lidocaine infiltrative anaesthesia is strongly suggested before performing laser treatment with DermaSCAN Unit.

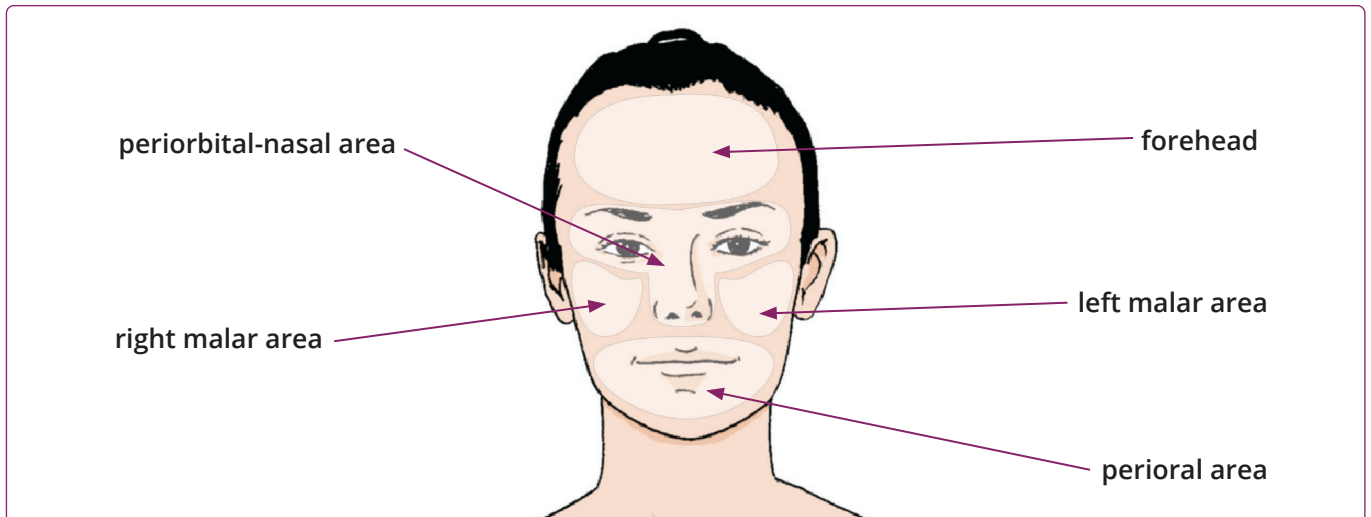
NOTE: If for short periods the user want to use the traditional emission modes HP, DP and SP (having the possibility to select the frequency), it is possible to turn off the scanner without disconnecting it from the articulated arm (SCAN OFF mode). In this way the system no longer displays the "DermaScan" screen but returns to the "freehand" one. The recommended parameters in SCAN OFF mode are those reported in the paragraph "Skin Surgery Procedures - Free Hand".

With the scanner off, carefully check that the pointer is clearly visible and centered.

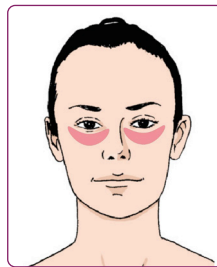
3.6 Fractional Treatment Procedure with DOT PRO

3.6.1 Aesthetic Units and Special Care for Dedicate Areas

The face is divided into five aesthetic units: right malar, perioral, left malar, forehead and periorbital-nasal areas. In case of laser skin resurfacing (both fractional and traditional) full face treatment is performed on each aesthetic unit sequentially, with care being taken to avoid overlapping.



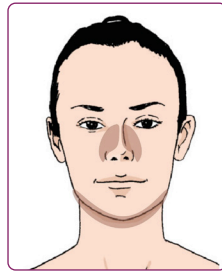
3.6.1.1 Special Care: Periocular Area



This area is very delicate. A common side effect is to have swelling and oedema. It is strongly suggested to follow the specific protocol for Upper and Lower Eyelids with the setting of SmartStack level equal to 1. It is recommended to decrease the fluence 3 in comparison to the “mild skin ageing” protocol.

→ Dwell Time ↓ → Energy per Pulse ↓ → Fluence ↓

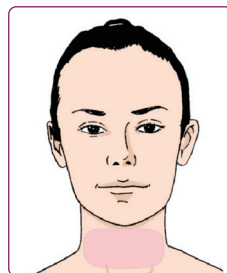
3.6.1.2 Special Care: Perinasal & Perimandibular Areas



In the perinasal area and in the submandibular area the risk of post treatment scars is high. It is recommended to decrease the fluence 20% less in comparison to the “mild skin ageing protocol”.

→ Dwell Time ↓ → Energy per Pulse ↓ → Fluence ↓

3.6.1.3 Special Care: Neck Area & Décolletage



This area is very delicate. A common side effect is to have swelling and oedema. It is strongly suggested to follow the specific protocol for Neck with the setting of SmartStack level equal to 1. It is recommended to decrease the fluence 30% less in comparison to the “mild skin ageing protocol”..

→ Dwell Time ↓ → Energy per Pulse ↓ → Fluence ↓

CLINICAL PROCEDURE

3.6.2 Fractional Standard Mode

In case of use of topical anaesthetic, it has to be removed just before the treatment.

Set the Tetra PRO system in DOT mode according to patient phototype, the area to be treated and the application. Usually we recommend performing a full-face and single passage treatment to obtain a better colour and texture uniformity.

The Tetra PRO offers the possibility to adapt the procedure according to the expectation of the patient: more or less aggressive treatment corresponds to longer or shorter down time after every session.

The "Energy per Pulse (in mJ)" and the "Fluence" (density of energy measured in J/cm²) delivered with the scanner is correlated with the effect provoked on the skin. The following formula allows to calculate the fluence level delivered in DOT mode:

$$\text{Fluence (J/cm}^2\text{)} = [\text{Power (W)} * \text{Dwell Time (ms)} * 10^5] / [\text{Spacing (}\mu\text{m)} + \text{SPOT}]^2 * \text{Stack}$$

As a simple result of the formula above, reducing the Power and/or the Dwell Time and/or increasing the Spacing, it is possible to reduce the fluence and to control the thermal effect on the skin.

The Energy per Pulse represents the total amount of mJ delivered over the same DOT, in which the effect of the Stack is already included in the calculation.

Before introducing the different protocols, the main differences in the impulses used in dermatology should be remembered:

- The D-Pulse and SmartPulse have a thermal component which is therefore important when a stimulation and shrinkage action is required or to coagulate.
- The H-Pulse is instead a cold pulse. A completely ablative pulse which, depending on the power level used and the selected stack, can have a very superficial and delicate action (also called Erbium-like) or be able to go deeper to debride for example the fibrotic scar tissues.

3.6.2.1 Atrophic Scars – “D-Pulse & SmartPulse” Protocols

NOTE: We remind you that DEKA has developed the **Scar 3 PRO** scanning system specifically for the scars treatment. The Scar 3 PRO scanner is used for a minimally invasive laser procedure of thickened scars of any severity, including deep contracted lesions and complex skin lesions.

An atrophic scar is an indented scar that heals below the normal layer of skin tissue.

An atrophic scar, given its nature and characteristics, usually benefits more from the use of pulses with a thermal component (as SP and/or DP) that favors tissue stimulation and shrinkage:

Mild Atrophic Scars - Forehead and Cheeks:

Skin Type	Power (W)	Dwell Time (µs)	Spacing (µm)	Stack (n°)	Pulse Mode
I-III	8	700	500	2	SP
IV-VI	15	500	1000	2	DP
Asian	6	400	700	1	DP

Severe Atrophic Scars - Forehead and Cheeks:

Skin Type	Power (W)	Dwell Time (µs)	Spacing (µm)	Stack (n°)	Pulse Mode
I-III	10	700	500	2	DP
IV-VI	20	500	1000	2	DP
Asian	5	400	500	2	SP

3.6.2.2 Atrophic & Hypertrophic Scars – “H-Pulse” Protocols

NOTE: We remind you that DEKA has developed the **Scar 3 PRO** scanning system specifically for the scars treatment. The Scar 3 PRO scanner is used for a minimally invasive laser procedure of thickened scars of any severity, including deep contracted lesions and complex skin lesions.

In some cases, such as for box acne scars, an atrophic scar has an important fibrotic component that must be treated before being able to stimulate or shrinkage the tissue. In these cases, the recommended initial treatment uses an H-Pulse and only subsequently (after one or 2 sessions, depending on the case) it is possible to switch to a more thermal action with the protocol that uses DP or SP pulses.

An HP cold pulse treatment is also suggested for darker or Asian phototypes.

CLINICAL PROCEDURE

Mild Atrophic Scars - Forehead and Cheeks:

Power (W)	Dwell Time (μs)	Spacing (μm)	Stack (n°)	Pulse Mode
8	-	400	2	HP

Severe Atrophic Scars - Forehead and Cheeks:

Power (W)	Dwell Time (μs)	Spacing (μm)	Stack (n°)	Pulse Mode
8	-	400	3	HP

A hypertrophic scar is a thick raised scar that's an abnormal response to wound healing. In these cases there is a need for a demolition action of the excess tissue. For this the election protocol uses an HP pulse.

Mild Hypertrophic Scars - Cheeks:

Power (W)	Dwell Time (μs)	Spacing (μm)	Stack (n°)	Pulse Mode
15	-	500	1	HP

Severe Hypertrophic Scars - Cheeks:

Power (W)	Dwell Time (μs)	Spacing (μm)	Stack (n°)	Pulse Mode
15	-	600	2	HP

Mild Hypertrophic Scars - Forehead:

Power (W)	Dwell Time (μs)	Spacing (μm)	Stack (n°)	Pulse Mode
15	-	700	1	HP

Severe Hypertrophic Scars - Forehead:

Power (W)	Dwell Time (μs)	Spacing (μm)	Stack (n°)	Pulse Mode
15	-	700	2	HP

3.6.2.3 Post Burn Scars – “H-Pulse” Protocols

NOTE: We remind you that DEKA has developed the **Scar 3 PRO** scanning system **specifically for the scars treatment**. The Scar 3 PRO scanner is used for a minimally invasive laser procedure of thickened scars of any severity, including deep contracted lesions and complex skin lesions.

Post Burn scars:

Power (W)	Dwell Time (µs)	Spacing (µm)	Stack (n°)	Pulse Mode
10	-	500	2	HP

3.6.2.4 Skin Ageing - “D-Pulse & SmartPulse” Protocols

The protocols shown in the following tables are indicated for the photorejuvenation of loose skin and/or with wrinkles. In addition to the superficial ablative effect, the thermal action of the DP and SP impulses allows to act more deeply in the dermis with an immediate shrinkage of the collagen as well as stimulating a subsequent neocollagenesis with a consequent improvement of skin appearance.

Mild Skin Ageing - Cheek and Forehead:

Skin Type	Power (W)	Dwell Time (µs)	Spacing (µm)	Stack (n°)	Pulse Mode
I-III	8	800	500	2	SP
IV-VI	15	700	800	1	SP
Asian	5	400	800	1	DP

Severe Skin Ageing - Cheek and Forehead:

Skin Type	Power (W)	Dwell Time (µs)	Spacing (µm)	Stack (n°)	Pulse Mode
I-III	8	1000	500	2	DP
IV-VI	20	200	800	2	SP
Asian	6	500	500	1	DP

CLINICAL PROCEDURE

Skin Ageing - Perioral:

Skin Type	Power (W)	Dwell Time (µs)	Spacing (µm)	Stack (n°)	Pulse Mode
I-III	8	500	400	2	DP
IV-VI	10	200	800	1	DP
Asian	5	500	600	1	DP

Skin Ageing - Periocular:

Skin Type	Power (W)	Dwell Time (µs)	Spacing (µm)	Stack (n°)	Pulse Mode
I-III	10	500	400	2	DP
IV-VI	10	500	800	1	DP
Asian	5	400	800	1	DP

Skin Ageing - Neck:

Skin Type	Power (W)	Dwell Time (µs)	Spacing (µm)	Stack (n°)	Pulse Mode
I-III	8	600	500	1	DP
IV-VI	10	700	800	1	DP
Asian	5	400	800	1	DP

3.6.2.5 Skin Ageing - "H-Pulse" Protocols

CO₂ laser treatment of dark or Asian skin should be done with caution due to the increased risk of PIH.

For these patients, in addition to the usual pre and post treatment recommendations, it is more suitable to choose a specific protocol that uses a cold pulse HP which, due to this characteristic, reduces the risk of inducing hyperpigmentation.

Mild Skin Ageing - Cheek and Forehead:

Power (W)	Dwell Time (µs)	Spacing (µm)	Stack (n°)	Pulse Mode
8	-	500	2	HP

Severe Skin Ageing - Cheek and Forehead:

Power (W)	Dwell Time (μs)	Spacing (μm)	Stack (n°)	Pulse Mode
12	-	500	2	HP

Skin Ageing - Perioral:

Power (W)	Dwell Time (μs)	Spacing (μm)	Stack (n°)	Pulse Mode
10	-	400	2	HP

Skin Ageing - Periocular:

Power (W)	Dwell Time (μs)	Spacing (μm)	Stack (n°)	Pulse Mode
10	-	400	1	HP

Skin Ageing - Neck:

Power (W)	Dwell Time (μs)	Spacing (μm)	Stack (n°)	Pulse Mode
10	-	500	1	HP

3.6.2.6 Coolpeel Treatment

The Coolpeel treatment is a treatment that allows to enjoy the benefits of the ablative laser on the more superficial layers of the skin with minimal down time. This treatment reduces fine lines, sun damage and pore size.

Coolpeel-Skin ageing:

Skin Type	Power (W)	Dwell Time (μs)	Spacing (μm)	Stack (n°)	Pulse Mode
I-III	3	-	600	1	HP
IV-VI	1	-	800	1	HP
Asian	2	-	800	1	HP

CLINICAL PROCEDURE

3.6.2.7 Superficial Benign Pigmented Lesion – “H-Pulse” Protocols

As mentioned before, for skin ageing protocols, in case of patient with dark and Asian skin type it is more suitable to choose a specific protocol that uses a cold pulse HP.

Diffuse pigmentary rejuvenation:

Power (W)	Dwell Time (μs)	Spacing (μm)	Stack (n°)	Pulse Mode
10	-	400	1	HP

3.6.3 Fractional Moveo Mode

The DOT PRO scanner can be used in two modes: Standard or Moveo mode (figure 1).

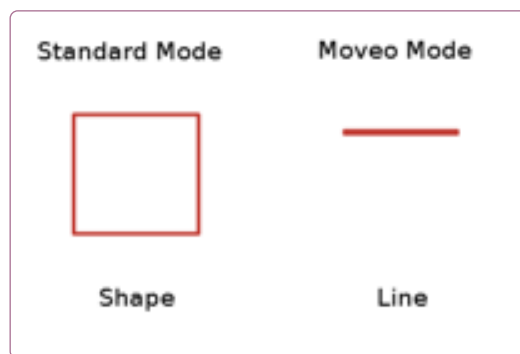


Figure 1. Fractional Mode: Standard and Moveo.

With the standard mode, the handpiece must be positioned perpendicular to the skin surface and must stay in the same position until the system has finished the entire scanning area (the user will hear a sound as soon as the scan is finished). After that the handpiece must be moved in such a way that there is no overlap between several scanning areas (Figure 2). This mode is used to treat severe disease such as acne scars and major rejuvenations (deep wrinkles).

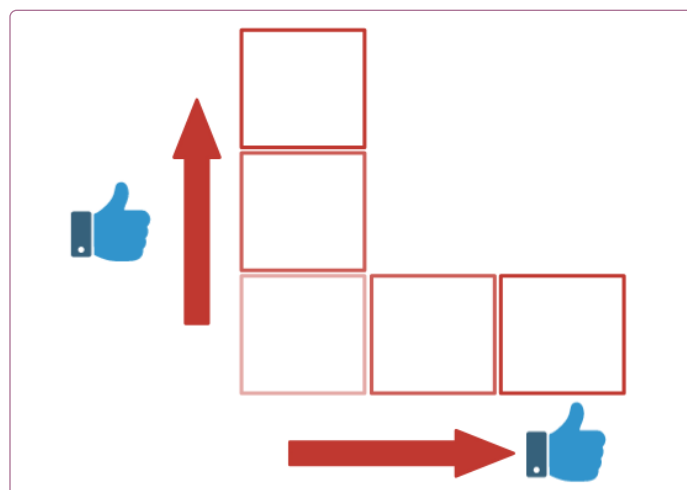


Figure 2. Fractional Standard Mode: the user can move the scanner in any direction but without overlapping the scan areas.

The moveo mode, on the other hand, consists of using the handpiece in motion. In this mode, the scanner performs a single line of DOTs, so it will be necessary to move perpendicular to the axis of the scan line as described in the figure below (Figure 3). This mode is used for mild rejuvenation treatments (e.g. fine wrinkles and coolpeel treatments).

NOTE: The scanner must remain in contact with the skin in both modes

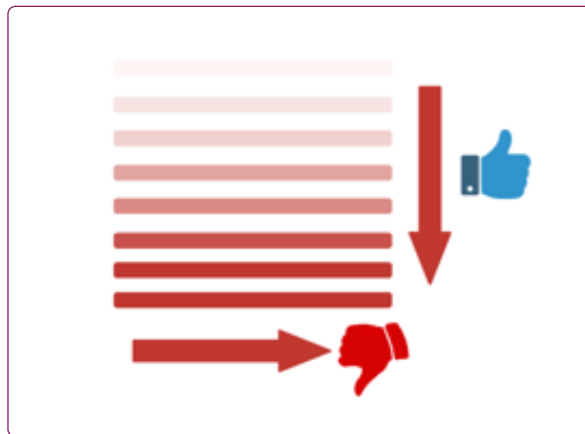


Figure 3. Fractional Moveo Mode: the user must move the scanner perpendicular to the axis of the scan line.

In the table below, the parameters for performing the skin test and identifying the most suitable treatment values are summarized. The working protocol has been drawn up with substantially conservative indications for obtaining initial efficacious results, minimum pain, minimum down-time and no side effects such as hyperpigmentation, hypopigmentation and blistering. These parameters allow users to increase either the working parameters or number of passes in order to achieve greater benefits, while monitoring the side effects, recovery time, tolerability and phototype requirements.

In fractional moveo mode, we suggest only one passage.

Since these values are purely indicative, they are not intended to replace or influence in any way the diligence, caution and competence of the operator. It is the physician's exclusive responsibility to select the appropriate treatment protocol for each patient based on an adequate check-up and individual case history.

Coolpeel – Skin ageing:

Skin Type	Power (W)	Dwell Time (μ s)	Spacing (μ m)	Stack (n°)	Pulse Mode
I-III	3	-	700	1	HP
IV-VI	1	-	700	1	HP
Asian	2	-	700	1	HP

CLINICAL PROCEDURE

Mild – Skin ageing:

Skin Type	Power (W)	Dwell Time (µs)	Spacing (µm)	Stack (n°)	Pulse Mode
I-III	10	-	700	1	HP
IV-VI	3	-	700	1	HP
Asian	6	-	700	1	HP

Severe– Skin ageing:

Skin Type	Power (W)	Dwell Time (µs)	Spacing (µm)	Stack (n°)	Pulse Mode
I-III	15	-	700	1	HP
IV-VI	5	-	700	1	HP
Asian	10	-	700	1	HP

3.7 Traditional Skin Resurfacing with CO₂ Laser with DOT PRO Scanner: Clinical Protocol

Each aesthetic unit has to be treated in its entirety avoiding overlap. Choose the appropriate shape and size of the scanning area. Set Power and Dwell Time according to the area to be treated. Please remember that with darker (III, IV, V and VI) and Asian phototypes, fractional skin resurfacing is strongly recommended.

Moist saline-soaked gauzes are used to remove debris during the procedure. This should be done gently to minimize additional tissue trauma. Debris removal is necessary to avoid a heat-sink phenomenon, which results in more thermal irritation of tissues.

Most areas are treated with a second pass. Approximately 30% of the time, a third pass is employed, a fourth is used in less than 5% of patients.

The endpoint of treatment is gauged to be ablation of wrinkles or “visual estimation to the reached layer”.

Skilled doctors could use more power and more dwell times than recommended in the protocol, avoiding multiple passes. In this case, please remember that skin removal is not proportional to the power increase whereas thermal damage is.

3.7.1 The Neck

As in chemical peeling exfoliation, the neck is not treated due to the risk of scarring. However, the perimeter can be treated with a single pass at the mandibular margin to avoid a frank line of demarcation between laser-resurfaced and non-resurfaced skin.

3.7.2 Malar Areas

For these areas the suggested setting is: Power= 17 W and Dwell Time= 200 μ s. Normally a second laser pass is used to treat the malar area, this should be done transversely with respect to the previous one.

3.7.3 Perioral Area

In the perioral area, laser resurfacing is carried on to the vermilion border. Great care is taken to avoid allowing the laser beam to strike teeth. Some surgeons prefer to use a protective mouth-piece. Be careful because it could distort the perioral tissue. Initial parameters should be: Power=15 W and Dwell Time= 200 μ s.

3.7.4 Forehead

When treating the forehead area, the hair is moistened and metal shields or moist towels are used to protect the eyes. Care is taken to avoid lasering the hairline or eyebrows. Initial parameters are: Power= 15 W and Dwell time= 200 μ s.

3.7.5 Periorbital Area

Because the eyelid tissue is so delicate, reduced Fluence is used: Power=10 W and Dwell Time= 200 μ s. The eye to be treated is anaesthetized with two drops of local anaesthetic. A glass or metal eye shield is inserted under the lid to protect the globe. It is better to use a spherical protector to be sure that the surface is smooth and free of any irregularities. Resurfacing is carried no closer than 3 to 4 mm from the ciliary margin to minimize oedema and possible thermal irritation to the Meibomian glands in the eyelid area. Multiple passes may be used to treat deep wrinkles in the lateral canthal area. For the upper eyelid, treatment is carried down to the superior tarsal fold.

3.8 Fractional Treatment Procedure with Scar 3 PRO

CO₂ laser treatment of dark or Asian skin should be done with caution due to the increased risk of PIH.

For these patients, in addition to the usual pre and post treatment recommendations, it is more suitable to choose a specific protocol that uses a cold pulse HP which, due to this characteristic, reduces the risk of inducing hyperpigmentation.

CLINICAL PROCEDURE

3.8.1 Deep Scars Mode (Depth > 1 mm)

Shallow scar (1-2 mm):

Power (W)	Dwell Time (μs)	Spacing (μm)	Stack (n°)	Pulse Mode
25	-	500	1	HP

Medium scar (2-3 mm):

Power (W)	Dwell Time (μs)	Spacing (μm)	Stack (n°)	Pulse Mode
30	-	500	1	HP

Deep scar (>3mm):

Power (W)	Dwell Time (μs)	Spacing (μm)	Stack (n°)	Pulse Mode
25	-	500	2	HP

3.8.2 Shallow Rejuvenation Mode (Depth < 1 mm)

3.8.2.1 Atrophic Scars - "D-Pulse & SmartPulse" Protocols

An atrophic scar is an indented scar that heals below the normal layer of skin tissue.

An atrophic scar, given its nature and characteristics, usually benefits more from the use of pulses with a thermal component (as SP and/or DP) that favors tissue stimulation and shrinkage.

Mild Atrophic Scars - Forehead and Cheeks:

Skin Type	Power (W)	Dwell Time (μs)	Spacing (μm)	Stack (n°)	Pulse Mode
I-III	5	700	500	2	SP
IV-VI	7	500	1000	2	DP
Asian	4	400	700	1	DP

Severe Atrophic Scars - Forehead and Cheeks:

Skin Type	Power (W)	Dwell Time (μs)	Spacing (μm)	Stack (n°)	Pulse Mode
I-III	8	700	500	2	SP
IV-VI	10	500	1000	2	DP
Asian	3	400	500	2	DP

3.8.2.2 Atrophic & Hypertrophic Scars – “H-Pulse” Protocols

In some cases, such as for box acne scars, an atrophic scar has an important fibrotic component that must be treated before being able to stimulate or shrinkage the tissue. In these cases, the recommended initial treatment uses an H-Pulse and only subsequently (after one or 2 sessions, depending on the case) it is possible to switch to a more thermal action with the protocol that uses DP or SP pulses.

An HP cold pulse treatment is also suggested for darker or Asian phototypes.

Mild Atrophic Scars - Forehead and Cheeks:

Power (W)	Dwell Time (μs)	Spacing (μm)	Stack (n°)	Pulse Mode
6	-	400	2	HP

Severe Atrophic Scars - Forehead and Cheeks:

Power (W)	Dwell Time (μs)	Spacing (μm)	Stack (n°)	Pulse Mode
6	-	400	3	HP

A hypertrophic scar is a thick raised scar that's an abnormal response to wound healing. In these cases there is a need for a demolition action of the excess tissue. For this the election protocol uses an HP pulse.

Mild Hypertrophic Scars - Cheeks:

Power (W)	Dwell Time (μs)	Spacing (μm)	Stack (n°)	Pulse Mode
10	-	500	1	HP

CLINICAL PROCEDURE

Severe Hypertrophic Scars - Cheeks:

Power (W)	Dwell Time (μs)	Spacing (μm)	Stack (n°)	Pulse Mode
10	-	500	2	HP

Mild Hypertrophic Scars - Forehead:

Power (W)	Dwell Time (μs)	Spacing (μm)	Stack (n°)	Pulse Mode
11	-	700	1	HP

Severe Hypertrophic Scars - Forehead:

Power (W)	Dwell Time (μs)	Spacing (μm)	Stack (n°)	Pulse Mode
11	-	700	2	HP

3.8.2.3 Post Burn Scars – “H-Pulse” Protocols

Post Burn Scars:

Power (W)	Dwell Time (μs)	Spacing (μm)	Stack (n°)	Pulse Mode
10	-	500	2	HP

3.8.2.4 Skin ageing - “D-Pulse & SmartPulse” Protocols

NOTE: We remind you that DEKA has developed the DOT PRO scanning system specifically for the skin rejuvenation treatment. The DOT PRO scanner is mainly used for a minimally invasive skin rejuvenation.

The protocols shown in the following tables are indicated for the photorejuvenation of loose skin and/or with wrinkles. In addition to the superficial ablative effect, the thermal action of the DP and SP impulses allows to act more deeply in the dermis with an immediate shrinkage of the collagen as well as stimulating a subsequent neocollagenesis with a consequent improvement of skin appearance.

Mild Skin Ageing - Cheek and Forehead:

Skin Type	Power (W)	Dwell Time (μs)	Spacing (μm)	Stack (n°)	Pulse Mode
I-III	5	800	500	2	SP
IV-VI	7	700	800	1	SP
Asian	3	400	800	1	DP

Severe Skin Ageing - Cheek and Forehead:

Skin Type	Power (W)	Dwell Time (μs)	Spacing (μm)	Stack (n°)	Pulse Mode
I-III	8	800	500	2	DP
IV-VI	10	200	800	2	SP
Asian	4	500	500	1	DP

Skin Ageing - Perioral:

Skin Type	Power (W)	Dwell Time (μs)	Spacing (μm)	Stack (n°)	Pulse Mode
I-III	12	1000	400	2	DP
IV-VI	5	200	800	1	DP
Asian	3	500	600	1	DP

CLINICAL PROCEDURE

Skin Ageing - Periocular:

Skin Type	Power (W)	Dwell Time (µs)	Spacing (µm)	Stack (n°)	Pulse Mode
I-III	10	500	400	1	DP
IV-VI	5	500	800	1	DP
Asian	3	400	800	1	DP

Skin Ageing – Neck:

Skin Type	Power (W)	Dwell Time (µs)	Spacing (µm)	Stack (n°)	Pulse Mode
I-III	5	500	500	1	DP
IV-VI	5	700	800	1	DP
Asian	3	400	800	1	DP

3.8.2.5 Skin Ageing - “H-Pulse” Protocols

NOTE: We remind you that DEKA has developed the DOT PRO scanning system specifically for the skin rejuvenation treatment. The DOT PRO scanner is mainly used for a minimally invasive skin rejuvenation.

CO₂ laser treatment of dark or Asian skin should be done with caution due to the increased risk of PIH.

For these patients, in addition to the usual pre and post treatment recommendations, it is more suitable to choose a specific protocol that uses a cold pulse HP which, due to this characteristic, reduces the risk of inducing hyperpigmentation.

Mild Skin Ageing - Cheek and Forehead:

Power (W)	Dwell Time (µs)	Spacing (µm)	Stack (n°)	Pulse Mode
6	-	500	2	HP

Severe Skin Ageing - Cheek and Forehead:

Power (W)	Dwell Time (µs)	Spacing (µm)	Stack (n°)	Pulse Mode
9	-	500	2	HP

Skin Ageing - Perioral:

Power (W)	Dwell Time (µs)	Spacing (µm)	Stack (n°)	Pulse Mode
7	-	400	2	HP

Skin Ageing - Periocular:

Power (W)	Dwell Time (µs)	Spacing (µm)	Stack (n°)	Pulse Mode
5	-	400	1	HP

Skin Ageing - Neck:

Power (W)	Dwell Time (µs)	Spacing (µm)	Stack (n°)	Pulse Mode
7	-	500	1	HP

3.8.2.6 Coolpeel Treatment

The Coolpeel treatment is a treatment that allows to enjoy the benefits of the ablative laser on the more superficial layers of the skin with minimal down time. This treatment reduces fine lines, sun damage and pore size.

Coolpeel-Skin ageing:

Skin Type	Power (W)	Dwell Time (µs)	Spacing (µm)	Stack (n°)	Pulse Mode
I-III	2	-	900	1	HP
IV-VI	1	-	900	1	HP
Asian	1	-	900	1	HP

CLINICAL PROCEDURE

3.8.2.7 Superficial Benign Pigmented Lesion

As mentioned before, for skin ageing protocols, for all patient and specially in case of patient with dark and Asian skin type it is more suitable to choose a specific protocol that uses a cold pulse HP.

Diffuse pigmentary rejuvenation:

Power (W)	Dwell Time (μs)	Spacing (μm)	Stack (n°)	Pulse Mode
7	-	400	1	HP

3.8.3 Fractional Moveo Mode

The Scar 3 PRO scanner can be used in two modes: Standard or Moveo mode (figure Y).

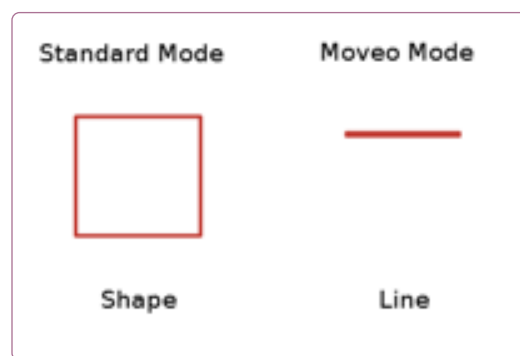


Figure Y. Fractional Mode: Standard and Moveo.

With the standard mode, the handpiece must be positioned perpendicular to the skin surface and must stay in the same position until the system has finished the entire scanning area (the user will hear a sound as soon as the scan is finished). After that the handpiece must be moved in such a way that there is no overlap between several scanning areas (Figure M). This mode is used to treat severe disease such as acne scars and major rejuvenations (deep wrinkles).

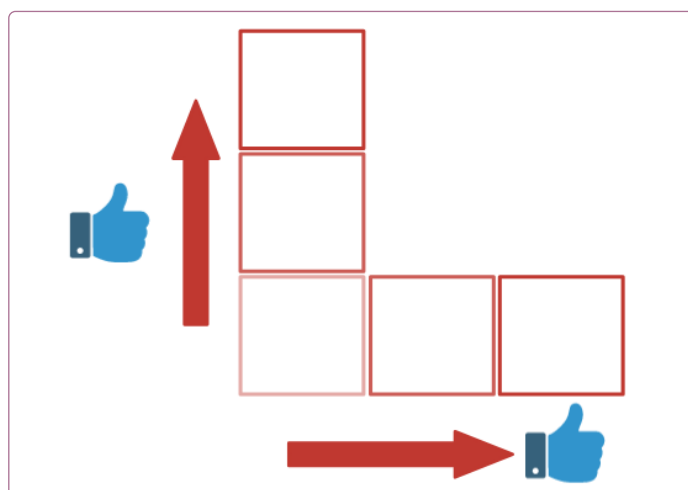


Figure M. Fractional Standard Mode: the user can move the scanner in any direction but without overlapping the scan areas.

The moveo mode, on the other hand, consists of using the handpiece in motion. In this mode, the scanner performs a single line of DOTs, so it will be necessary to move perpendicular to the axis of the scan line as described in the figure below (Figure N). This mode is used for mild rejuvenation treatments (e.g. fine wrinkles and coolpeel treatments).

NOTE: The scanner must remain in contact with the skin in both modes

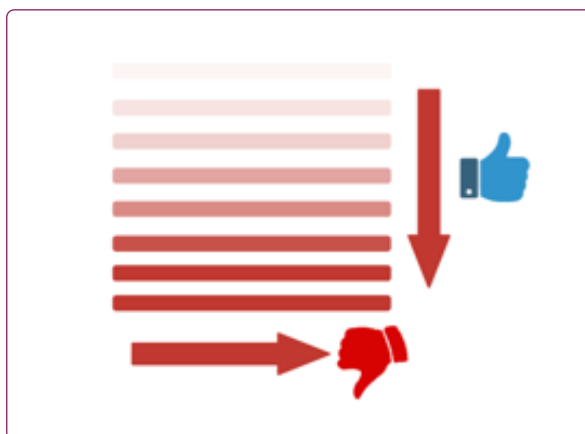


Figure N. Fractional Moveo Mode: the user must move the scanner perpendicular to the axis of the scan line.

In the table below, the parameters for performing the skin test and identifying the most suitable treatment values are summarized. The working protocol has been drawn up with substantially conservative indications for obtaining initial efficacious results, minimum pain, minimum down-time and no side effects such as hyperpigmentation, hypopigmentation and blistering. These parameters allow users to increase either the working parameters or number of passes in order to achieve greater benefits, while monitoring the side effects, recovery time, tolerability and phototype requirements.

CLINICAL PROCEDURE

In fractional moveo mode, we suggest only one passage.

Since these values are purely indicative, they are not intended to replace or influence in any way the diligence, caution and competence of the operator. It is the physician's exclusive responsibility to select the appropriate treatment protocol for each patient based on an adequate check-up and individual case history.

Coolpeel – Skin ageing:

Skin Type	Power (W)	Dwell Time (µs)	Spacing (µm)	Stack (n°)	Pulse Mode
I-III	2	-	700	1	HP
IV-VI	1	-	700	1	HP
Asian	2	-	700	1	HP

Mild – Skin ageing:

Skin Type	Power (W)	Dwell Time (µs)	Spacing (µm)	Stack (n°)	Pulse Mode
I-III	7	-	700	1	HP
IV-VI	2	-	700	1	HP
Asian	4	-	700	1	HP

Severe– Skin ageing:

Skin Type	Power (W)	Dwell Time (µs)	Spacing (µm)	Stack (n°)	Pulse Mode	Pulse Energy (mj)
I-III	12	-	700	1	HP	33.0
IV-VI	4	-	700	1	HP	11.0
Asian	7	-	700	1	HP	22.0

3.9 Post Treatment Care

Operations carried out with laser devices generate thermal injury, abrasion or ablation of the skin which makes daily care of the wound essential. Therefore, side effect are expected and must be differentiated from complication.

The aim is to achieve healing, preventing the formation of scabs in the middle and on the inner edges of the area treated, and thus guaranteeing an adequate cleanliness and softness.

Nearly all patient encounter minor side effects ranging from postoperative pain and oedema to pruritus and tightness. In order to reduce the swelling and the inflammation that may occur after the procedure of fractional skin resurfacing, we recommend applying on the skin, just after the treatment, cool compression or wet gauzes cooled using the Cryo6 air jet. A mild serous (watery) discharge could be seen, which subsides spontaneously after 2/3 days.

As post-treatment care, execute a medication with accurate gentle skin cleansing, cold packs compression which must always be carried out with sterile gauze and physiological solution. Patient must re-applies every time emollient and/or antibiotic and enzymatic ointments, especially after cleaning and showers.

This procedure has to be performed 3-4 times per day until the clinical healing is observed (4-7 days typically). After this time, apply a normal skin-care moisturizer and a sunblock protection (for 2-5 months according to the skin phototype and the environmental conditions).

It is suggested to wait for 1 day before having a shower (avoid hot water on the treated area until healing is complete). Avoid sun exposure for at least 2 weeks (in case of more invasive treatments it is strongly suggested to avoid sun exposure for 4 weeks).

The use of moisturizing and emollient lotions is suggested without time limitation: it helps in maintaining the uniform and compact aspect of the new skin.

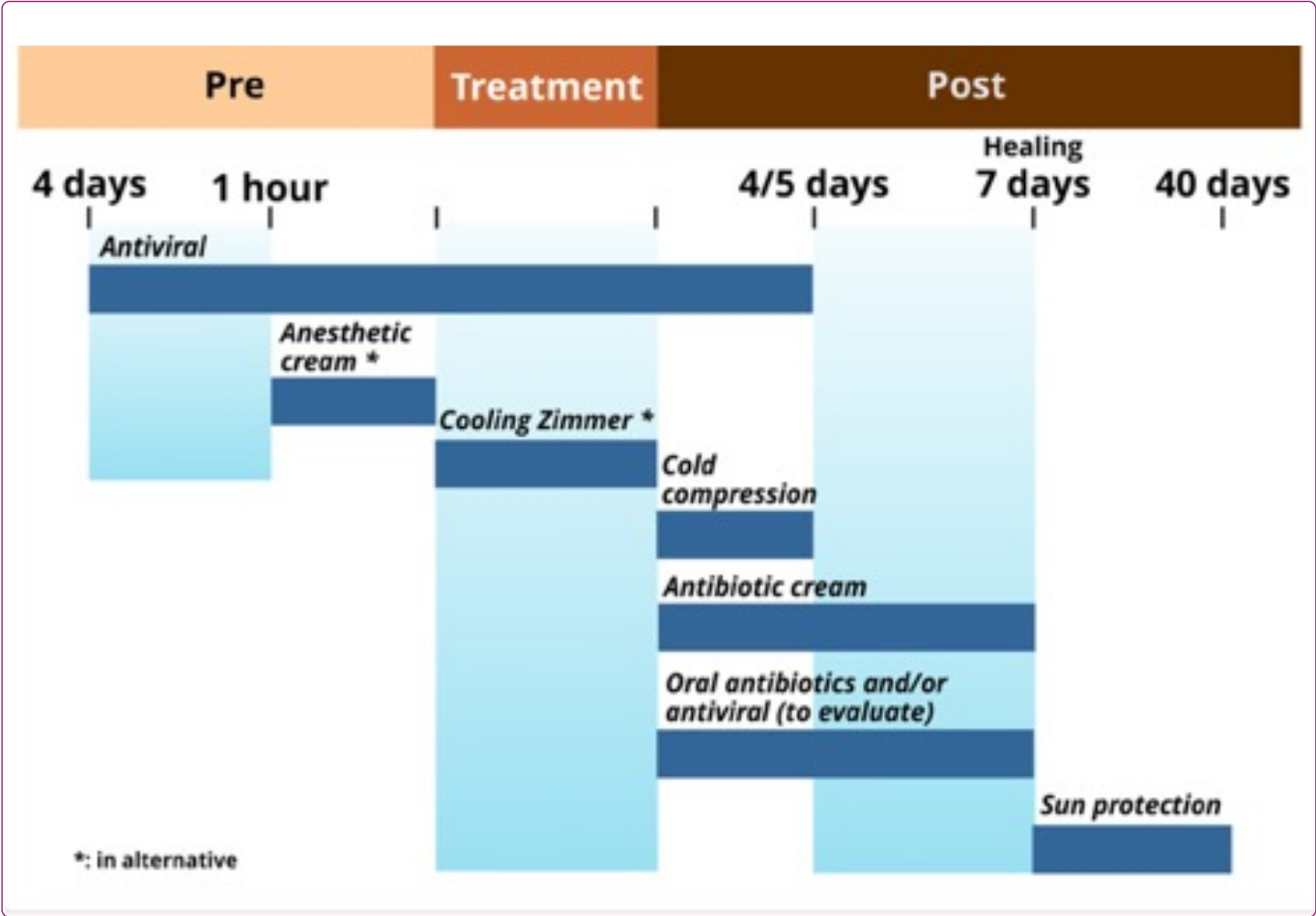
N.B.: The patient must immediately call the physician in the event of any side effects such as excessive reddening, infections or blistering. The physician will judge whether it is necessary to use antibiotic creams.

CLINICAL PROCEDURE

3.10 Repeating the Fractional Treatments

The majority of patients observe increased skin tone and texture after the first fractional treatment. The results will be visible immediately after the first session, but continue to develop for 3-6 months. The doctors should evaluate a plan of fractional sessions at varying intervals depending on the area to be treated and to the severity (Fluence and energy per pulse) of the treatment. In general it's suggested to repeat the fractional treatment after 2-3 months. The following treatment can be carried out if the tissue has completely healed.

3.11 Treatment Management – Summary Table





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